PMAC 2017
ACCESS TO MEDICINES:
HOW TO FIX THE BROKEN SYSTEM

Changing R&D model

DNDi
Drugs for Neglected Diseases *initiative*

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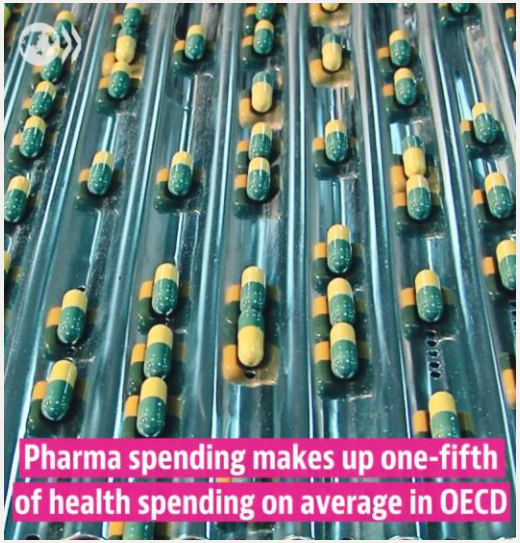
2016 MSF report: "The way it is conducted today, Research and Development (R&D)…"

- Do not deliver for diseases that are not sufficiently lucrative
  - No investment in drugs, diagnostics and vaccines for people who cannot afford them
- Do not prioritize according to public health needs
  - E.g. antibiotics, anti-tuberculosis
- Do not deliver affordable products
  - Exclusive patent rights preventing competition (eg. Cancer drugs, DAAs)
- Does not use scientific and financial resources efficiently and effectively
  - Isolation, competition, secrecy, redundancy

MSF Access Campaign: Lives on the edge: time to align medical research and development with people's health needs 2016

http://www.oecd.org/health/managing-new-technologies-in-health-care (Jan 2017)



Political leadership at the center of solutions

- Government must demand transparency
- Governments must change incentive mechanisms to steer and finance biomedical innovation
  - Use all the legal tools at their disposal to ensure access and resist demands for additional exclusivity rights
  - Reclaim more than the product itself for their investment
    - incentives and publicly funded basic/translational research
  - Embrace new approaches that de-link R&D costs and product price (eg. product development partnerships)
- Acting on behalf of patients, governments must set priorities and coordinate efforts

MSF Access Campaign: Lives on the edge: time to align medical research and development with people's health needs 2016

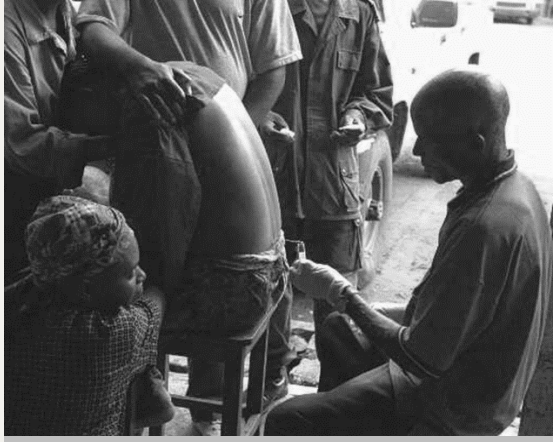
Origins of DNDi

1999

- First meeting to describe the lack of R&D for neglected diseases
- MSF commits the Nobel Peace Prize money to the DND Working Group
- JAMA article: 'Access to essential drugs in poor countries - A Lost Battle?'

July 2003

- Creation of DNDi
- Founding partners:
    - Institut Pasteur, France
    - Indian Council of Medical Research, India
    - Kenya Medical Research Institute, Kenya
    - Médecins Sans Frontières
    - Ministry of Health, Malaysia
    - Oswaldo Cruz Foundation/Fiocruz, Brazil
    - WHO –TDR (Special Programme for Research and Training in Tropical Diseases) as a permanent observer



DNDi approach: Address immediate patient needs & deliver innovative medicines - Short- and long-term

New chemical entities (NCEs)

New formulations

New indications for existing drugs

Completing registration dossier

Geographical extension

Long-term projects

Medium-term projects

Short-term projects

Research → **Translation** → **Development** → **Implementation**

> 5 years

3-5 years

1-2 years

Sleeping sickness

Chagas disease

Filarial diseases

Leishmaniasis

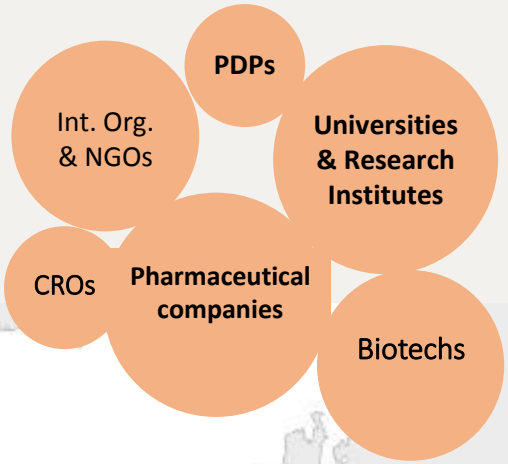
Mycetoma

Malaria

Paediatric HIV

Hepatitis C

DND*i*'s virtual R&D organization: Success only possible through innovative partnerships

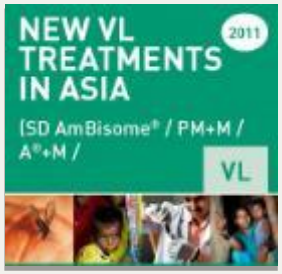


Over 160 partnerships worldwide

CRITERIA FOR SUCCESS

- ✓ Share the same vision
- ✓ Mutual understanding
- ✓ Involvement throughout the whole process

7 new treatments delivered, recommended, implemented



- ✓ Easy to use
- ✓ Affordable
- ✓ Field-adapted
- ✓ Non-patented

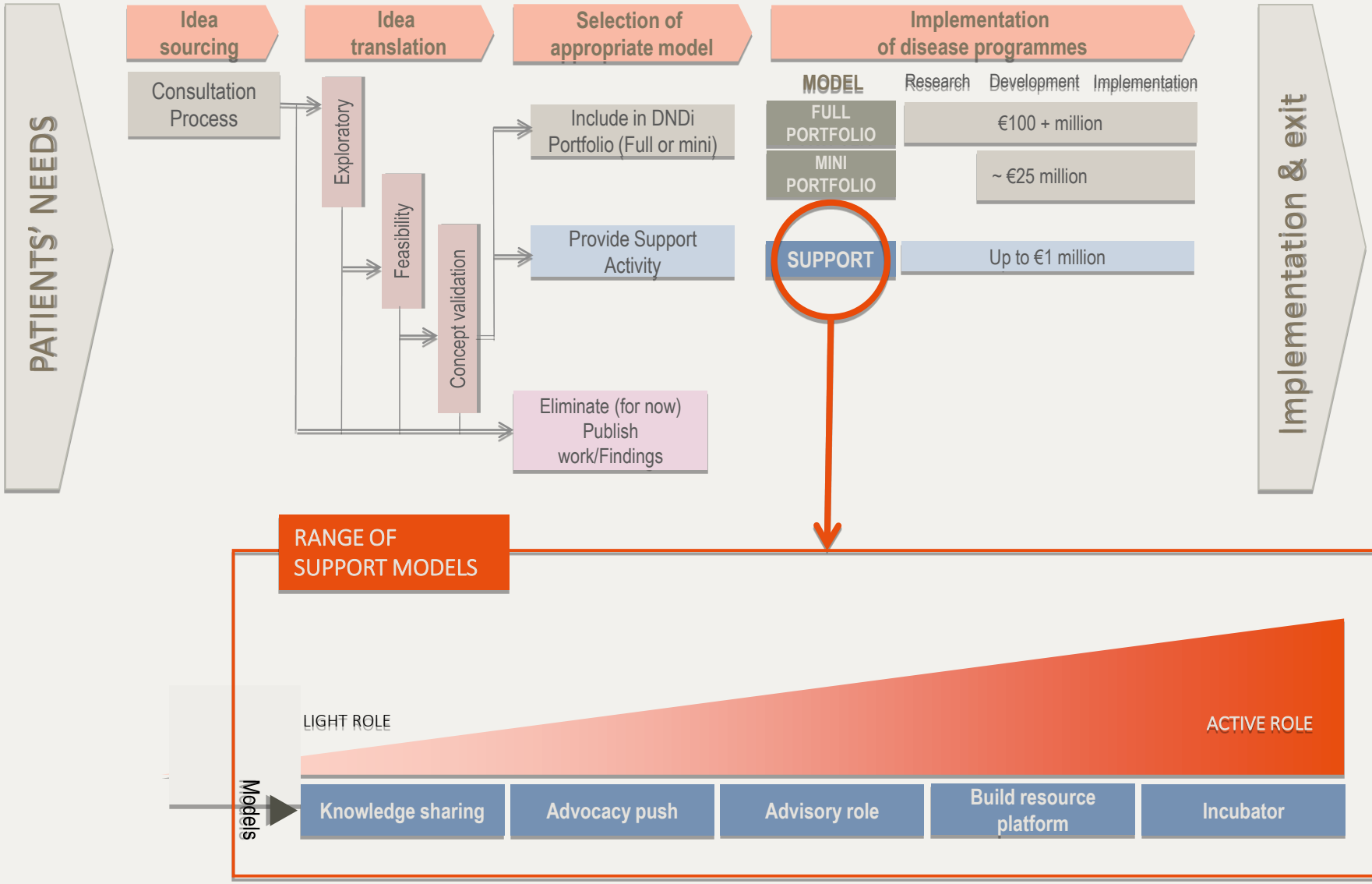
- **30 projects, 8 diseases areas**
- **13 entirely new chemical entities (NCEs)**
- **Over 160 partnerships,** most in endemic countries
- **160 staff**, half in endemic countries & 700 people working on DNDi projects
- **EUR 400 million** raised equally from public and private sources
- **4 regional disease-specific clinical trial platforms/ networks** and several technology transfers

Diversification of donors: EUR 400M secured out of EUR 650M to deliver 16-18 treatments by 2023

- 50% public - 50% private
- max. 25% per donor

=> Delinkage between R&D funding and final product pricing

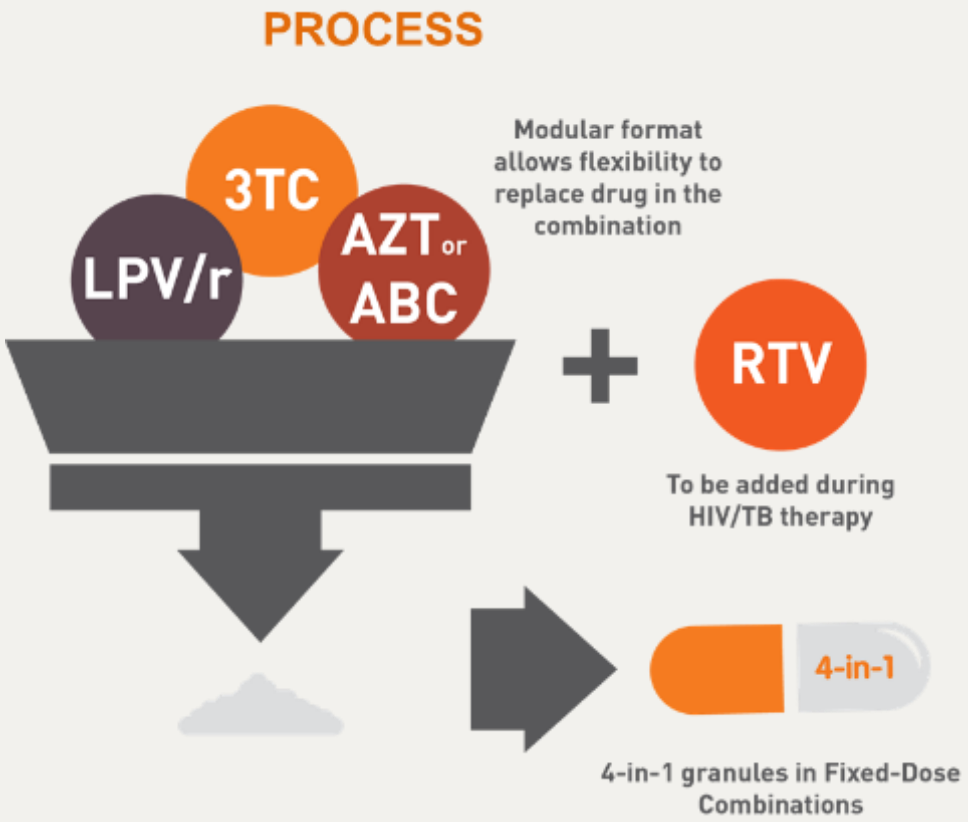
How do we do it… operationally



For each disease, a Target Product Profile is developed to guide decisions (e.g. paediatric HIV)

IDEAL CHARACTERISTICS (TPP)

- 4 ARVs in one
- Simple to open and use with water, milk, food
- Good taste
- No fridge needed
- Suitable for infants (<2 months - 3 years)
- TB-treatment compatible
- Affordable for governments



Paediatric HIV: Scaling up with the right tools, right now and bringing '4-in-1's formulations for children

Today

LPV/r

Only available treatment for young children: unpalatable (42% alcohol), requires refrigeration, expensive, difficult to store and transport

2016

'Super-boosting' ritonavir is recommended by WHO in ARV guidelines 2016 for **TB/HIV** co-infected children

By 2018

To deliver:

- 2 new **'4-in-1's** child-appropriate formulations that are safe, easy to administer, well-tolerated & heat-stable

Sleeping sickness: Two new treatments in development to support sustainable elimination

13 years ago

Melarsoprol:

Toxic, resistant

Eflornithine:

Not available

Since 2009

NECT

Improved therapy

2018?

Fexinidazole

Oral treatment (10 days)

Future objective

SCYX-7158

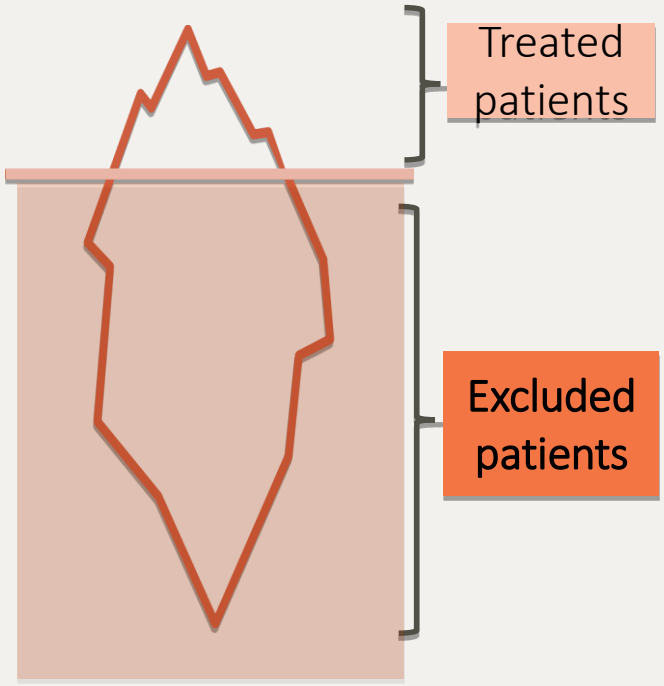
Single-dose, oral treatment

NECT = Nifurtimox-Eflornithine

Dynamic portfolio: New disease areas, new models…

Neglected patients

Hepatitis C



Public health approach

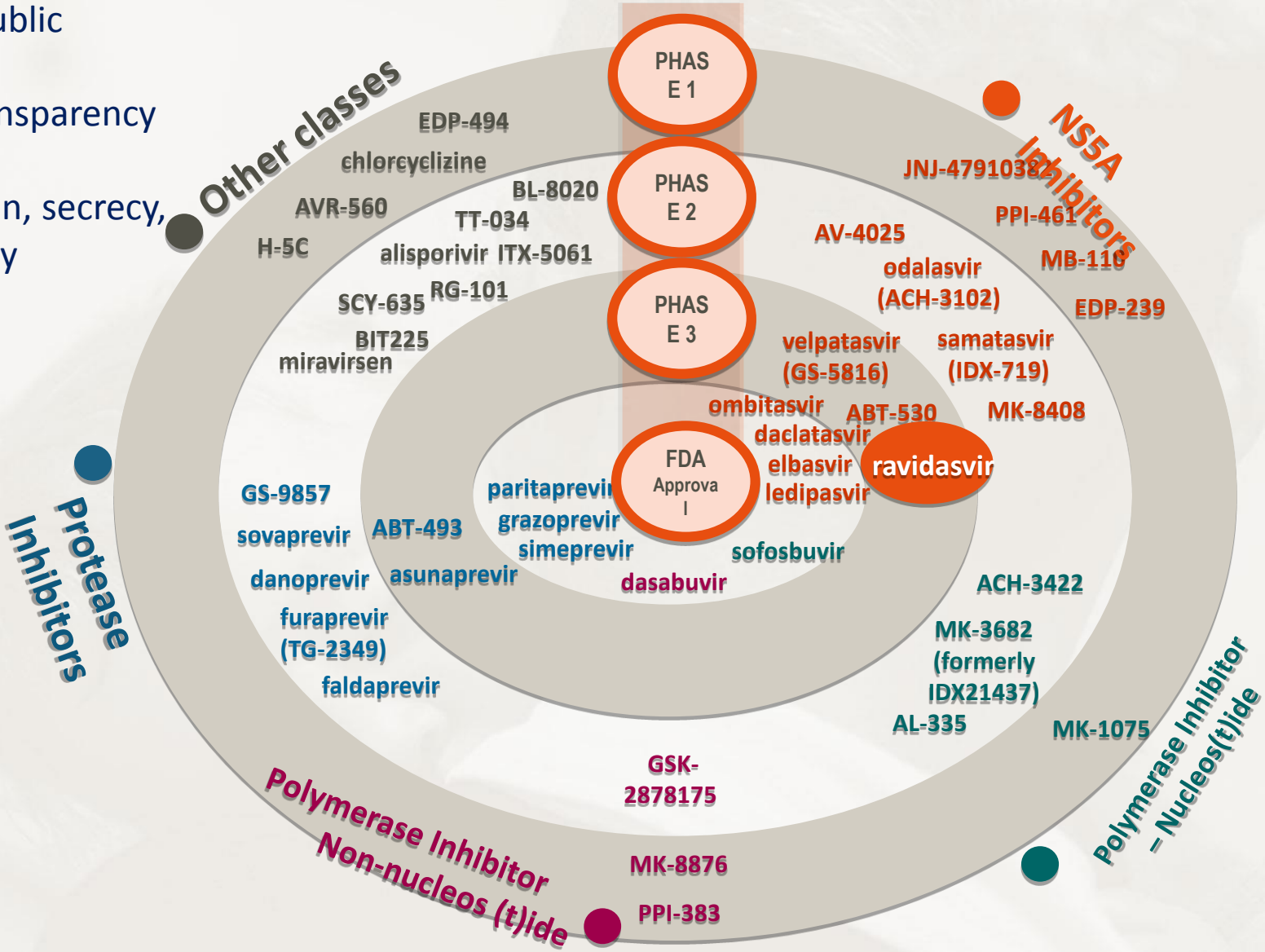
Neglected models

Antimicrobial resistance

Incubation of GARD

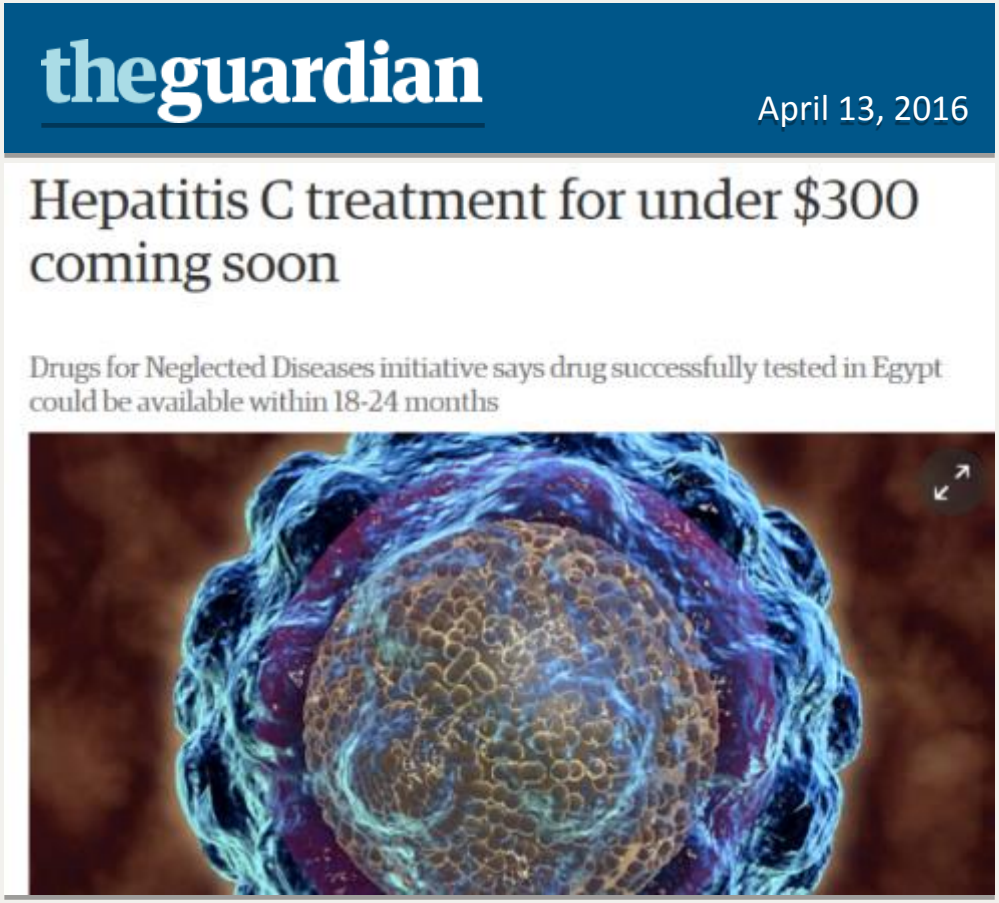
Abundant R&D pipeline… but many drug candidates abandoned

- Massive public funding
- Lack of transparency
- Isolation, competition, secrecy, redundancy



A pan-genotypic treatment for less than $300

- DND*i*, Pharco and Presidio agreement to test combination of sofosbuvir + ravidasvir
- Partnership with Malaysia and Thailand to conduct Phase II/III multicentre study (900 patients)
- Using innovative licensing agreement or TRIPS flexibilities



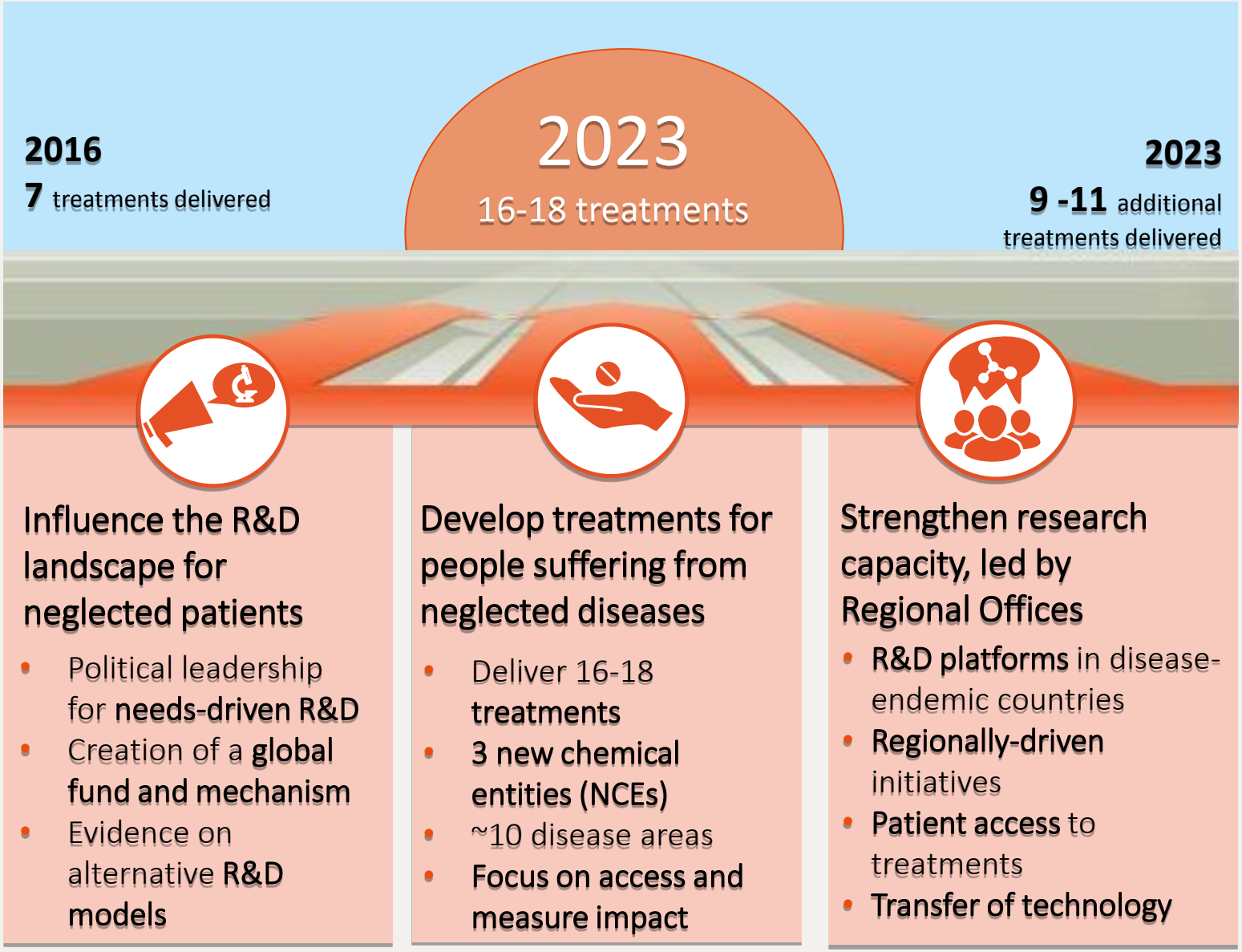
theguardian

April 13, 2016

Hepatitis C treatment for under $300 coming soon

Drugs for Neglected Diseases initiative says drug successfully tested in Egypt could be available within 18-24 months

By 2023: Deliver 16 to 18 treatments with EUR 650 million




Thank you very
much for your
attention
DNDi
Drugs for Neglected Diseases initia

- Backup slides

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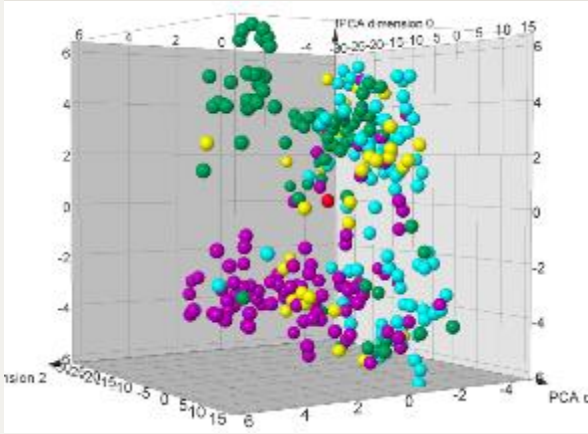
The NTD Drug Discovery Booster

- Objective: speed up the process and cut the cost of finding new treatments for leishmaniasis and Chagas disease
- Booster launched in 2015
- 3 Japanese pharma companies on board since the start
- Innovation: multilateral and cross-company comparative approach + iterative search
- Already 6 seed compounds submitted to the booster and > 1,600 analogues tested

AstraZeneca Eisai Takeda SHIONOGI Celgene DNDi Drugs for Neglected Diseases initiative Institut Pasteur Korea GHIT Fund Global Health Innovative Technology Fund



Innovation & Access on the political agenda: Influencing the R&D landscape for neglected patients

13 years of discussions at WHA, with 6 resolutions (2003-2016)

- **2003** CIPIH
- **2006** IGWG
- **2008** Expert Working Group on R&D
- **2010** CEWG
- **2013** Demo projects, Global R&D Obs.
- **2016** Priority setting role Obs., voluntary pooled fund, core principles, delinkage

Connect the dots

- R&D Blueprint for Emerging Pathogens
- July 2016: UN High-Level Panel on Access to Medicines
- September 2016: UN High-Level Meeting on AMR

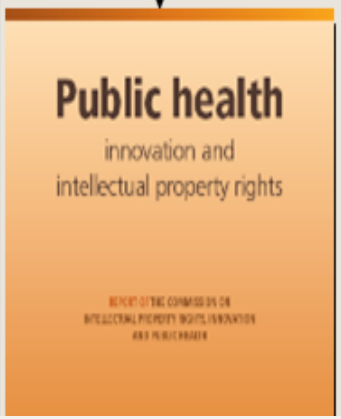
Over 10-Year Discussion at World Health Assembly Level to Find a Sustainable Solution

2003

Resolution WHA56.27

Intellectual property rights, innovation and public health

Commission on Intellectual Property Rights, Innovation and Public Health



2006

Resolution WHA59.24

Public Health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action

Intergovernmental Working Group

2008

Resolution WHA61.21

Global strategy and plan of action on public health, innovation and intellectual property

Expert Working Group on Research and Development: Financing and Coordination

2010

Resolution WHA63.28

Establishment of a consultative expert working group on research and development: financing and coordination

Consultative Expert Working Group on Research and Development: Financing and Coordination

2013

Resolution 66.22

Governments agree to experiment demonstration projects, set up a global R&D observatory, explore the set up of pooled fund, resume in 2016 open-ended meeting

May **2016**
WHO Open-ended meeting

Need to develop an overarching framework: priority-setting, sustainable funding, and principles

Funding for R&D initiatives

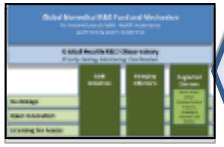
NIH National Institutes of Health

wellcome trust

USAID FROM THE AMERICAN PEOPLE

ruta n MEDELLÍN

GHIT Fund
Global Health Innovative Technology Fund



BILL & MELINDA GATES foundation

BNDES The Brazilian development bank

DFID

UNITAID

EUROPEAN COMMISSION

EDCTP

...and others

Global Biomedical R&D Fund and Mechanism

For innovations of Public Health importance

governed by public leadership

Global Health R&D Observatory

Priority-Setting, Monitoring, Coordination

De-linkage

Open Innovation

Licensing for Access

AMR

Emerging Infections (incl. Ebola)

Poverty Related / Neglected Diseases