

Neglected Tropical Diseases:

Balancing the Fatal Imbalance

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Presentation Outline

- Neglected Tropical Diseases (NTDs)
- The Fatal imbalance
- Addressing the imbalance
- DNDi's contribution
 - The role of disease specific Platforms
 - WHO
 - WHA CEWG
 - The London Declaration
 - Drug Regulation in Africa
- Way forward



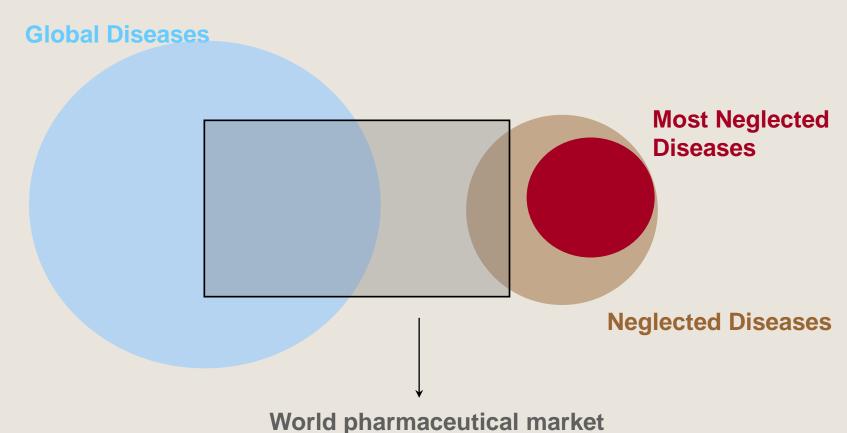
The Landscape

Neglected Tropical Diseases





Neglected Diseases: Primarily Affect Developing Countries & Lie Outside the World Market



\$856 bn in 2010*
nearly \$1,100 bn forecast by 2015



*Source: IMS Health

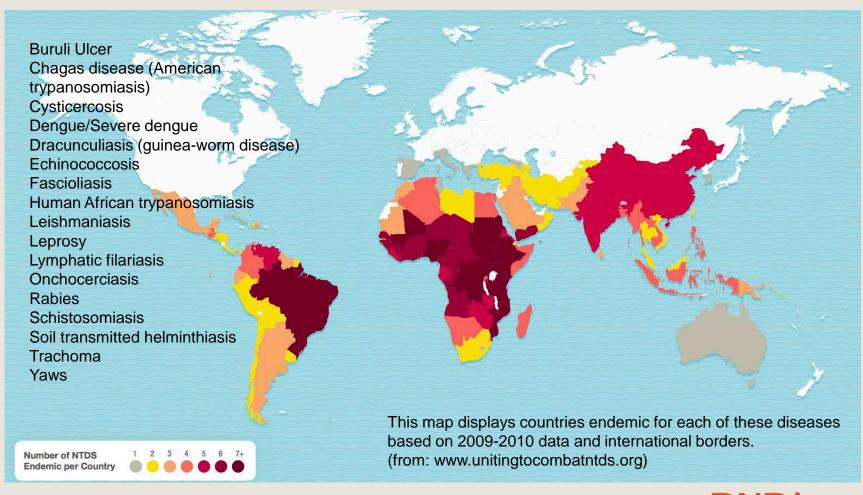
WHO List of Neglected Tropical Diseases

- Buruli Ulcer
- Chagas disease (American trypanosomiasis)
- Cysticercosis
- Dengue/Severe dengue
- Dracunculiasis (guinea-worm disease)
- Echinococcosis
- Fascioliasis
- Human African trypanosomiasis
- Leishmaniasis

- Leprosy
- Lymphatic filariasis
- Rabies
- Schistosomiasis
- Soil transmitted helminthiasis
- Trachoma
- Yaws
- Onchocerciasis
- Podoconiosis
- Mycetoma
- Scabies
- Stongylodiasis



Burden of Neglected Tropical Diseases



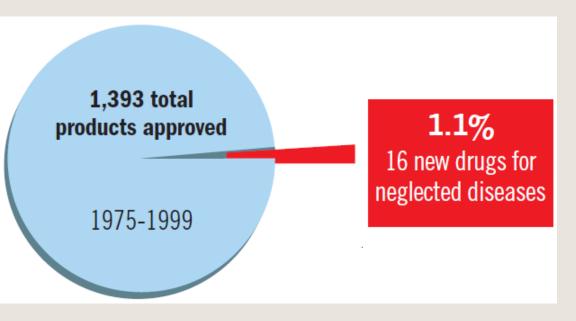


The Fatal Imbalance



A Decade Ago, Pipeline Virtually Empty for Neglected Diseases

Health R&D (1975 - 1999)



A Fatal Imbalance

From 1975-1999:

- 16 of 1393 new products for neglected tropical diseases + malaria and TB (1.1%) despite these diseases representing 12% of global disease burden
- approx. 10% of R&D dedicated to illnesses that affect 90% of global disease burden ('10/90 gap')



Source: Fatal Imbalance: The Crisis in Research and Development for Neglected Diseases, MSF, 2001

The R&D Gap

The drug and vaccine landscape for neglected diseases (2000—11): a systematic assessment

Belen Pedrique, Nathalie Strub-Wourgaft, Claudette Some, Piero Olliaro, Patrice Trouiller, Nathan Ford, Bernard Pécoul, Jean-Hervé Bradol

Published in October 2013

The Lancet Global Health





Objective of the Study

Reassess the state of R&D for neglected diseases compared to other diseases over 2000-2011 based on:

- Approved products
- Ongoing clinical trials



Methods: selection of diseases

49 infectious and parasitic diseases, selected out of existing lists:

- WHO list of NTDs,
- Trouiller et al, Hotez et al,
- PLOS Neglected Tropical Diseases journal disease scope,
- G-FINDER 2011 report,
- BIO Ventures for Global Health 2012 report

5 categories

- TB
- malaria
- diarrheal diseases
- neglected tropical diseases according to WHO
- Other neglected diseases



Methods: approved products

- All products approved across all indications from 1
 January 2000 to 31 December 2011
- Sources:
 - EMA and US FDA;
 - Databases of countries* belonging to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S)
 - WHO List of Prequalified Medicinal Products and the WHO Essential Medicines List used as a proxy measure of medical benefit

Drugs for Neglected Diseases initiative

^{*} Belgium, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Portugal, Spain, Sweden, The Netherlands, United Kingdom, Canada, Australia, Switzerland, Iceland, Argentina; Japan, India and Brazil.

Methods: approved products (2)

- New products classified into:
 - new chemical entity (NCE)
 - new indication (NI)
 - new formulation (NF)
 - fixed-dose combination (FDC)
 - vaccine or biological product



Methods: clinical trials review

- Data bases: (Sep 1999-Dec 2011)
 - Phase I-III clinical trials listed in the US National Institutes of Health (NIH) (ClinicalTrials.gov)
 - WHO registry of clinical trials
- 31 December 2011 "Snapshot" of active trials
- Clinical trial sponsors were classified into
 - public institutions (e.g Fiocruz)
 - private not-for-profit organisations (e.g PDPs)
 - private industry/for-profit entity (e.g pharmaceutical industry)
 - multiple-sponsors.



Clinical Trials Findings

Clinical trials between 1999-2011

- All diseases:148,445
- Neglected diseases: 2,016 (1%)

In on going clinical trials for Neglected diseases:

- 123 new products being tested
- 55% (68/123) are vaccines and biological products, including 21 against malaria.
- □ 28% (34/123) are new products for NTDs

or Neglected Diseases initiative

Study Conclusion

- A persistent imbalance between disease burden and product development for NTDs.
- A major R&D gap remains in NCEs for NTDs, both in terms of new approvals and ongoing clinical development
- Malaria, TB, and diarrheal diseases remain the primary focus of productdevelopment research, with little or no focus at all on NTDs





Addressing the Imbalance (1)

The DNDi's Model - Contribution to R&D for NTD's for 10 years





Since 1999, from ideas to realization

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 (7 founding members)





DND*i*: Patient Needs-Driven & Innovative R&D Model

- Deliver 11 to 13 new treatments by 2018
- Establish a robust pipeline
- Use and strengthen existing capacity in disease-endemic countries
- Raise awareness and advocate for increased public leadership

Founding Partners

- Indian Council for Medical Research (ICMR)
- Kenya Medical Research Institute (KEMRI)
- Malaysian MOH
- Oswaldo Cruz Foundation, Brazil
- Médecins Sans Frontières (MSF)
- Institut Pasteur France
- TDR (permanent observer)



Responding to the Needs of Patients Suffering from Neglected Diseases





Malaria

Leishmaniasis

Paediatric HIV



Sleeping Sickness (HAT)



Chagas Disease

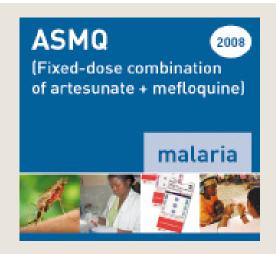


Filaria



6 New Treatments Developed Since 2007

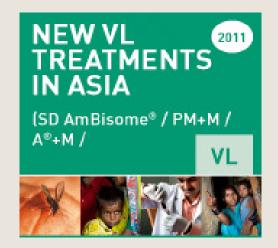






☑ Easy to Use ☑ Affordable ☑ Field-Adapted ☑ Non-Patented







Partnerships: No One Can Do It Alone A Global Network to Leverage Resources



Disease Specific Platforms

Endemic country contibution to NTD research



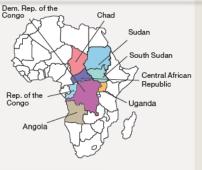


Utilizing and Strengthening Research Capacities in Disease-Endemic Countries

VL









CHAGAS



Clinical Research Platforms

- Defining patient needs and TPP
- Strengthening local capacities
- Conducting clinical studies (Phase II/III)
- Facilitating registration
- Accelerating implementation of new treatments

Transfer of technology

Data Management Centre – Nairobi

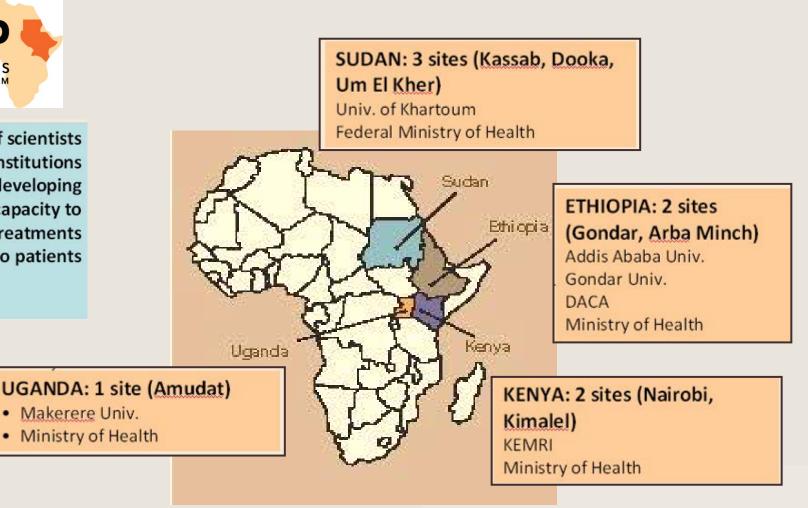
Drugs for Neglected Diseases initiative

- Clinical sites with good practices
- Building networks of excellence (i.e. ANDi)

Leishmaniasis East Africa Platform (LEAP)



A group of scientists and institutions working on developing clinical trial capacity to bring new treatments to patients



LEAP collaborates with

Challenge to Conduct Clinical Trials in Very Difficult Settings



- Access to Sites
- Status of Infrastructure
- Staff Limitations







Addressing the Imbalance (2)

- The WHO Road Map
- WHA CEWG
- The London Declaration
- Drug Regulation in Africa





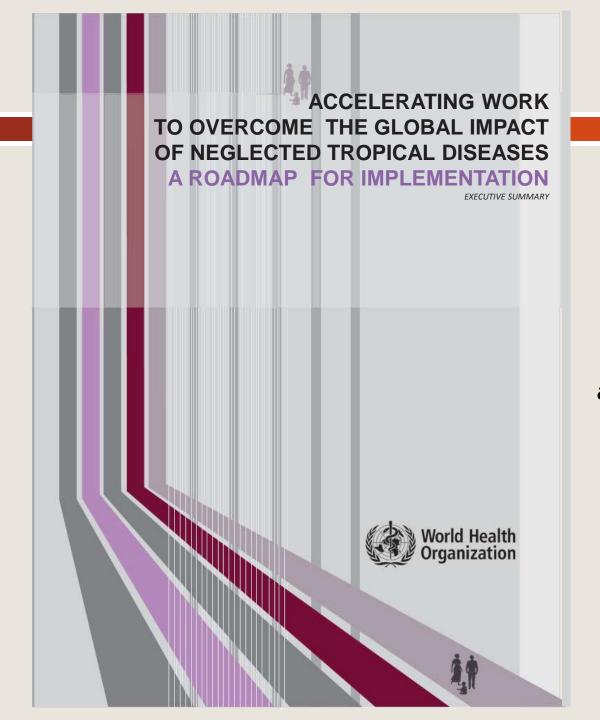
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The WHO Road Map

Accelerating work to overcome the global impact of neglected tropical diseases

January 1, 2012





"This roadmap for implementation represents the next step forward in relieving and, in many cases, finally ending the vast misery caused by these ancient diseases of poverty".

Dr Margaret Chan, Director-General, World Health Organization

Printed in France.

Reprinted: March and April 2012

WHO Road Map

In 2003, WHO began to focus control measures away from specific diseases to the health needs of poor communities.

This led to the introduction of two major strategic interventions:

- Preventive chemotherapy
- Intensified disease management



Other Measures

- Control of vectors and their intermediate hosts veterinary public health
- Water and sanitation
- Health awareness
- Education
- Capacity building



2

WHA - CEWG

- WHO Consultative Expert Working Group
- Kenya Brazil Resolution





BACKGROUND & POLICY CONTEXT 10 year political process in WHO

2003 2006 2008 2010

Resolution WHA56.27

Intellectual property rights, innovation and public health

Commission on Public Health, Innovation and Intellectual Property Rights

Resolution WHA59.24

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

Intergovernmental Working Group

Resolution WHA61.21

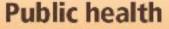
Global strategy and plan of action on public health, innovation and intellectual property

Expert Working Group

Resolution WHA63.28

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

Consultative Expert Working Group (CEWG)



innovation and intellectual property rights

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Coordination and Financing

Report of the Expert Working Group



- (a) take forward the work of the Expert Working Group;
- (b) deepen the analysis of the proposals in the Expert Working Group's report, and in particular: (i) examine the ... four innovative sources of financing proposed (ii) review the five promising proposals ...; and (iii) further explore the six proposals that did not meet the criteria ...
- (c) consider additional submissions and proposals

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The London Declaration

Inspired by the World Health Organization's 2020 Roadmap on NTDs

Launched 30st January 2012

Webcast at KEMRI





Endorsed – 19 institutions

- 1) Abbott
- 2) Bayer
- 3) Becton Dickinson
- 4) Bill & Melinda Gates
 Foundation
- 5) Bristol-Myers Squibb
- 6) DNDi
- 7) Eisai
- 8) Gilead
- 9) GlaxoSmithKline

- 10) Johnson & Johnson
- 11) Merck KGaA
- 12) **MSD**
- **13)** Mundo Sano
- 14) Novartis
- 15) Pfizer
- 16) Sanofi
- 17) UKaid
- 18) USAID
- 19) World Bank



The London Declaration

we commit to doing our part to:

Ensure the necessary supplement	ly of	drugs an	d other	interventi	ons to	help
eradicate Guinea worm disea	se					

Eliminate by 2020 lymphatic filariasis, leprosy, sleeping sickness (human African trypanosomiasis) and blinding trachoma.

Control by 2020 schistosomiasis, soil	-transmitted helmintl	nes, Chagas
disease, visceral leishmaniasis and rive	r blindness (onchoce	erciasis).

☐ Advance R&D through partnerships and provision of funding to find next-generation treatments and interventions for neglected diseases.



The London Declaration

we commit to doing our part to:

☐Enhance collaboration and coordination on NTDs at national and international levels
☐Enable adequate funding with endemic countries to implement NTD programmes
☐Provide technical support, tools and resources to support NTD-endemic countries to evaluate and monitor NTD programmes.
☐Provide regular updates on the progress in reaching the 2020 goals and identify remaining gaps.



London Declaration: Call To Action

To achieve this ambitious 2020 vision, we call on all endemic countries and the international community to join us in the above commitments by:

- providing the resources necessary across sectors to remove the primary risk factors for NTDs—poverty and exposure
- ensuring access to clean water and basic sanitation, improved living conditions, vector control, health education, and stronger health systems in endemic areas.



4

Drug Regulation in Africa







FIRST BIENNIAL SCIENTIFIC CONFERENCE ON MEDICINES REGULATION IN AFRICA

Birchwood Hotel | Johannesburg – South Africa | 2-3 December, 2013 ABSTRACTS | DEC 2013

Conference Theme:

Building Partnerships for Sustainable Capacity Development in Medicines Regulation in Africa



FIRST BIENNIAL SCIENTIFIC CONFERENCE ON MEDICINES REGULATION IN AFRICA

Issues addressed:

- ☐ Global regulatory environment Where is Africa?
 - Continental Progress and updates EAC noted as a best practice
 - Regional initiatives for strengthening regulatory systems
 - Harmonisation of medicines regulatory requirements
- □ Regulatory Harmonization, Capacity development and partnership
 - EDCTP Network of Excellence
 - Creating a regulatory profession
 - Role of Academia in Medicines regulation



The Way Forward

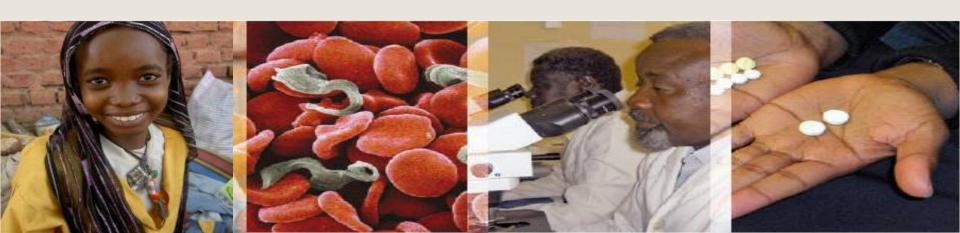
Addressing the challenges in Africa to balance the fatal imbalance





We need to build innovation and clinical research capacities in Africa

- Public African leadership needed
- Strengthen Sustainable Research capacities
- Stimulate transfer of technologies to Africa
- Strong partnerships and South-South collaborations
- Strengthen Regulatory environment
- Governments to take more responsibility for health of citizens
- Translation of clinical research results into policy
- Collaboration between PDPs and MOH to facilitate access to new tools





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