

# **Noordwijk Medicines Agenda**

**Changing the Face of Innovation for  
Neglected and Emerging Infectious Diseases**

**Infectious diseases**

**Innovation**

**Development**

**Policy coherence**

**Networks**

**R&D incentives**

**Open innovation**



# **NOORDWIJK MEDICINES AGENDA**

***CHANGING THE FACE OF INNOVATION FOR  
NEGLECTED AND EMERGING INFECTIOUS DISEASES***



ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

## **ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT**

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## **PREFACE**

The OECD High-Level Forum on Medicines for Neglected and Emerging Infectious Disease: Policy Coherence to Enhance their Availability (HLF) was organised in collaboration with the government of the Netherlands.

Improving global health is a shared responsibility. The HLF was attended by high level officials of developed and developing countries, and senior representatives from industry, the scientific community, international and non-governmental organisations who met to contribute a coherent, open agenda for action. They met to build a coherent, open agenda for action in that would stimulate innovation and radically accelerate the development and delivery of medicines, vaccines and diagnostics for neglected and emerging infectious diseases that disproportionately affect developing countries. While participants made it clear that many health issues in developing countries cannot be solved by the development of new health technologies alone, such technologies are nevertheless important: efforts to accelerate innovation and to reduce poverty and its consequences must therefore go hand and hand.

The High-Level Forum called upon: governments both of OECD and developing countries to demonstrate political leadership and to join with industry, product development partnerships, investors, shareholders, intergovernmental organisations and non-governmental organisations to further intensify collaborative efforts and promote coherent policies to improve the availability of and access to medicines, vaccines and diagnostics for neglected and emerging infectious diseases.

The result of this call to action is the Noordwijk Medicines Agenda (NMA) which is a summary of the main themes of the OECD High-Level Forum on Medicines for Neglected and Emerging Infectious Disease: Policy Coherence to Enhance their Availability. It represents a general agreement of participants about the problems, goals, and work that needs to be done in order to improve the availability of medicines for neglected and emerging infectious diseases. The NMA has not been formally endorsed by OECD countries.

The discussions and conclusions from the High-Level Forum are being brought together in a Report that will be published by the OECD by spring 2008.

## SYNOPSIS

### ***The OECD High-Level Forum on Medicines for Neglected and Emerging Infectious Disease: Policy Coherence to Enhance their Availability***

Countries in the Organization for Economic Cooperation and Development (OECD) account for about 80% of gross expenditure in research and development globally. But the health innovation systems of OECD countries are failing to deliver the new health products needed to combat neglected infectious diseases of the developing world. New medicines are needed for many infectious diseases including: Human African Trypanosomiasis; Leishmaniasis; Schistosomiasis; Chagas disease; Lymphatic filariasis and onchocerciasis. There are many challenges to the development and delivery of such medicines; problems associated with the safety, stability, formulation of medicines as well as resistance. Under the current framework for innovation, companies have few incentives to assume the costs and risks of putting a new medicine onto the market, mainly because the target markets in developing countries are not profitable enough. Low returns on investment combined with high developmental risks discourage investment in R&D.

The OECD High-Level Forum capitalised on the growing international movement in favour of improving incentives for investment in research, development and delivery of medicines, vaccines and diagnostics for neglected and emerging infectious diseases. The objective was to identify concrete actions and policy options that would promote an open innovation strategy and help deliver a new generation of technologies for infectious diseases. The *Noordwijk Medicines Agenda*, represents a general consensus of the meeting regarding the problems, goals, and work that needs to be undertaken in order to improve the availability of medicines for neglected and emerging infectious diseases.

The Forum recognized that OECD countries have a strong self-interest in combating infectious diseases. In addition to the humanitarian reasons why countries should be involved in fighting infectious diseases in developing countries, there are both economic and security reasons why OECD countries should be concerned. Pathogens can spread far from where they first developed due to increases in trade, international tourism and climate change. Severe Acute Respiratory Syndrome (SARS) exemplified how an infectious disease may quickly transcend borders, triggering important economic ripple effects globally.

The Forum considered what measures would increase incentives for investment in R&D, improve the pipeline of new health technologies for infectious diseases, and create a more efficient and reactive innovation system. Many participants voiced strong support for a more open innovation system that might involve one or multiple virtual networks of researchers from both developed and developing countries. Networks which encouraged common infrastructures and shared knowledge bases might yield economies of scale. The success of existing initiatives (*e.g.* WHO/TDR, and Product Development Partnerships) suggests how a model of open innovation might be broadened to address multiple infectious diseases, and indeed any market which is small, fragmented or deemed commercially “unprofitable”.

Participants at the High-Level Forum agreed there was a need for a coherent, cross-ministry, political message about the importance of improving the availability of medicines for neglected and emerging infectious diseases. While it was clear that many health issues in developing countries cannot be solved by developments in health technologies alone, such technologies are nevertheless important. Policies are needed to create an innovation environment that will rapidly deliver new medicines for multiple diseases. Participants discussed the pros and cons of different “push” and “pull” policy mechanisms designed to spur innovation in medicines for neglected infectious diseases. The HLF reasserted the need to monitor the effectiveness of these various mechanisms and to better understand what mix of mechanisms is appropriate in different circumstances.

The Noordwijk Medicine’s Agenda has identified a set of coherent policies that if implemented could radically increase research and development in new drugs, vaccines and diagnostics for infectious diseases and that would provide the visionary leadership and policy innovation, to help enable developing countries to finally beat the scourge of infectious diseases.

OECD is considering several streams of analytical work relevant to the actions in the Noordwijk Medicines Agenda. The OECD would like to provide a strong foundation for evidence-based policymaking. Its working method encourages dialogue between different branches of government, and civil society including: industrial actors, research organisations, NGOs and philanthropies. Governments are exploring what policy actions will stimulate R&D and encourage translational research in infectious diseases. But the policy mix necessary needs to be better understood. The proposals for OECD analysis include:

1. Facilitating the scale up of global virtual collaborative drug development R&D networks for neglected infectious diseases.
2. Exploring the utility of collaborative mechanisms for access and use of IPRs and the application of open innovation tools for R&D in neglected infectious diseases.
3. Evaluating the effectiveness of new policies and research models for promoting R&D in infectious diseases (Advanced Market Commitments, Prizes, new R&D funds).

## THE NOORDWIJK MEDICINES AGENDA

NOORDWIJK AAN ZEE, THE NETHERLANDS, 21 JUNE 2007

### *The High-Level Forum*

#### *Recognises that:*

- Infectious diseases have a serious socio-economic impact in addition to the burden placed on health systems, particularly in developing countries.
- It is in the economic interest of all countries to mobilise resources for the control of neglected and emerging infectious diseases, bearing in mind that incentives to address neglected and emerging diseases may differ and that both sets of diseases require international and national attention.
- Research and development (R&D) is essential to make available innovative, safe and effective medicines, vaccines, and diagnostics for neglected and emerging infectious diseases and thus to achieve, in the long term, a sustainable response to major global health challenges. Continued investment in basic science is essential to feed innovation in health.
- Access to affordable essential drugs and availability of the benefits of new technologies is a core element of development as identified in the Millennium Development Goals (Goal 8), which calls for a global partnership in this area.
- Work to improve the availability and accessibility of medicines, vaccines and diagnostics for neglected and emerging infectious diseases that primarily affect developing countries is ongoing in international organisations such as the World Health Organisation (WHO) and in other international partnerships and bodies.
- A number of recently created public and private initiatives, (*e.g.* public-private product development partnerships (PDPs) and industry philanthropic programmes) have increased research and development on some neglected infectious diseases and raised international awareness of the extent of the problem.
- Many developing countries do not have the research infrastructure to address R&D for neglected diseases.
- Functioning health systems in developing countries are necessary to ensure access to care and basic medicines.
- Innovation includes both the development of new healthcare products and the delivery and diffusion of those products, and any efforts to improve the availability of medicines, vaccines, and diagnostics must be accompanied by efforts to improve access to health care and to strengthen health systems.

***Acknowledges that:***

- In both developed and developing countries, there is an urgent need for greater policy coherence in health, science, development, trade, finance and industry policies in order to tackle neglected and emerging infectious diseases, as well as a need to increase policy makers' understanding of the interdependencies of these policy areas.
- The WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) presents a unique opportunity to reach international agreement on an integrated framework for accelerating innovation and improving access to medicines in the developing world. As well as mobilizing more concerted efforts of governments, industry, research institutes and non-governmental organizations, such a framework would help to strengthen coherence among international organizations and initiatives.
- OECD governments have taken promising initial steps to establish long-term predictable financing to meet the Millennium Development Goals, but more effort is required.
- The protection and use of intellectual property rights (IPRs) are important in encouraging investments in research and development of medicines, vaccines, and diagnostics but are not sufficient to stimulate innovation for neglected and emerging infectious diseases. Complementary reward systems may also play an important role.
- Product development partnerships (PDPs) are an innovative and potentially successful model of collaborative R&D that leverage industry investments and foster innovation to increase the availability and accessibility of health technologies. They, as well as some other recent initiatives, lack long term sustainable financing and alone are not sufficient to foster innovation throughout the entire innovation cycle, from the test tube to the patient.
- Long-term development aims for medicines for neglected diseases should include not only incentives for R&D in OECD countries, but incentives to increase R&D and technology capacity in developing countries.
- New approaches to more open innovation and collaborative research, as well as access to knowledge, can further increase the efficiency and lower the costs of developing new, safe and effective medicines, vaccines and diagnostics for neglected and emerging infectious diseases as well as broaden the involvement of researchers, academic institutions, laboratories and companies globally.
- Activities in pharmaceutical innovation, manufacturing and trade are increasingly crossing national borders, which necessitate enhanced collaboration among, and strengthening of, regulatory agencies to ensure safety, quality and efficacy of healthcare products as well as to maintain public trust.
- The capacity of developing countries and their institutions must be strengthened and utilised in order to foster their contribution to global R&D efforts, and to ensure that innovation reaches the patients most in need.
- Continued efforts must be made to engage a broad range of stakeholders to ensure policy coherence and take forward the elements of this agenda.

*The High-Level Forum calls upon: governments both of OECD and developing countries to demonstrate political leadership and to join with industry, product development partnerships, investors, shareholders, intergovernmental organisations and non-governmental organisations to further intensify collaborative efforts and promote coherent policies to improve the availability of and access to medicines, vaccines and diagnostics for neglected and emerging infectious diseases.*



*Actions should focus on the following areas:*

1. Exploring in conjunction with the WHO/IGWG process how greater efforts to collaborate in prioritising, developing and delivering innovative medicines, vaccines and diagnostics could increase investments and the number of researchers involved in R&D for neglected and emerging infectious diseases that primarily affect developing countries. Specifically:
  - Pursuing the viability of a global, virtual collaborative drug development network drawing on existing initiatives, including those of the WHO/TDR, PDPs, and regional (*e.g.* south-south and north-south) technology networks.
  - Facilitating the development and operation of a sustainable architecture for the sharing and exchange of knowledge, data and research tools necessary for the discovery of medicines, vaccines and diagnostics for neglected and emerging infectious diseases.
  - Identifying the infrastructure needs to underpin such efforts to accelerate the discovery of medicines, vaccines and diagnostics for neglected and emerging infectious diseases.
  - Forecasting effective demand for essential medical technologies.
  - Ensuring that there is sustained high level political support and adequate funding for the WHO/IGWG activities including implementation of the Global Strategy and Plan of Action.
  - Considering the African Health Strategy and the Pharmaceutical Manufacturing Plan for Africa adopted by the African Union Health Ministers in April 2007.
2. Exploring and evaluating for-profit and not-for-profit models to promote innovation and stimulate the development of new medicines, vaccines and diagnostics for neglected and emerging infectious diseases primarily affecting developing countries. In particular explore:
  - The potential value of sustainable collaborative mechanisms for IPRs (such as patent pools or other IP and data management entities). This work could be carried out by the OECD as part of its ongoing work on collaborative mechanisms for IPRs in co-operation with other relevant international organisations.
  - Alternative policy mechanisms to reward innovation (*e.g.* advanced market commitments, prize fund models, valorisation of intellectual assets) to better understand how these could contribute to the development of medicines, vaccines and diagnostics for neglected and emerging infectious diseases. The strengths and limitations of alternative mechanisms could be considered, as well as monitoring pilot phases of existing mechanisms. This should involve empirical testing.
  - Comprehensive and inclusive approaches to innovation that place delivery of new health technologies to patients at its core.
  - Mechanisms to promote the transfer of technology, knowledge and technical skills to strengthen developing country innovation systems.
  - Supporting and providing incentives to new models of partnerships between developing and developed countries to accelerate R&D for neglected diseases.

- Synergies and complementarities between research and development financing to support R&D in developing countries by harmonising OECD Official Development Assistance (ODA) mechanisms.
- The use of existing flexibilities of multilateral agreements to foster innovation and access.

3. Supporting developing countries-led efforts in strengthening their own health, local production and research systems, including prevention, to ensure availability and accessibility of medicines, vaccines, diagnostics and other preventative technologies for neglected and emerging infectious diseases in accordance with the principles of the Paris Declaration on Aid Effectiveness (March 2005). In particular:

- Improving predictability and transparency of funding including official development assistance.
- Taking steps to strengthen the capability of developing countries to manage issues of intellectual property, including using available flexibilities to the fullest extent, and to build sustainable networks and capacity for global research.



**09:10–10:15      SESSION 1: THE ECONOMICS OF FIGHTING INFECTIOUS DISEASES**

**Chair:**      *Angel GURRÍA*, OECD Secretary-General

<i>Harvey RUBIN</i>	University of Pennsylvania, Institute for Strategic Threat Analysis and Response, United States
<i>Tido von SCHOEN-ANGERER</i>	Médecins Sans Frontières, Switzerland
<i>Hannah KETTLER</i>	Bill and Melinda Gates Foundation, United States
<i>Ruth LEVINE</i>	Center for Global Development, United States
<i>Adrian TOWSE</i>	Office of Health Economics, United Kingdom

***Speakers to address:***

- Why do OECD countries have economic interests in addressing poverty related diseases that predominately affect developing countries?
- What factors could change the economic consequences of infectious disease (globalisation, ageing, climate change)?
- Can we forecast demand for treatment and prevention in the developing world?
- What are the trends on R&D for infectious diseases that predominately affect developing countries?
- What level investment in R&D is necessary to generate safe and effective new drugs/vaccines/diagnostics for infectious diseases that predominately affect developing countries?

**10:15–10:50      *COFFEE BREAK FOR ALL PARTICIPANTS, IN THE PRESENCE OF HER MAJESTY THE QUEEN IN THE “IMPERIAL BAR”***

***(Departure of Her Majesty the Queen from the Hotel at around 10.50)***

**11:00–12:00      SESSION 2: CREATING INCENTIVES FOR R&D  
INVESTMENTS: THE POLICY OPTIONS**

**Chair:** *Howard ZUCKER*, Assistant Director-General, Health Technology and Pharmaceutical, WHO, Switzerland

<i>Michael KREMER</i>	Harvard University, United States
<i>Carlos MONTICELLI</i>	Ministry of Economics and Finance, Italy
<i>Julian SCHWEITZER</i>	The World Bank, United States
<i>Suresh JADHAV</i>	Serum Institute of India, India
<i>José Francisco GARCIA-BUSTOS</i>	GlaxoSmithKline, Spain
<i>Amit SACHDEV</i>	Biotechnology Industry Organisation, United States

***Moderated roundtable discussion:*** The past ten years has seen the birth of a large number of “push and pull” mechanisms to promote research and development for diseases that affect the developing world including: advance purchase commitments; public private partnerships for medicine development; global purchase funds; prizes; philanthropic R&D institutes; and international technology transfer networks. This session focuses on the ability of these policy mechanisms to deliver a sustainable pipeline of new products and to create new R&D capacity globally.

- What is the measure of success for these mechanisms and what has been their record?
- Which are likely to accelerate the development of safe, effective and affordable medicines for diseases that disproportionately affect developing countries?
- Which are economically sustainable over the long term?
- Which are helping to create a competitive climate for R&D?
- Can they build R&D capacity globally? Do laboratories and companies in developing countries participate?

**12:00-12:05      *Welcome on behalf of City Council of Noordwijk by the Mayor* -Harry GROEN**

**12:05-12:20      *Drinks offered by the City Council of Noordwijk – Imperial Bar***

**12:30-13:45      *BUFFET LUNCH – for all participants in the Oranje Nassau Windsor  
Lunch by invitation – Ministers’ lunch hosted by Ab KLINK, Minister of Health,  
Welfare and Sport, The Netherlands – Hermitage Salon***

**14:00–15:00      SESSION 3:      NEW DRUGS FOR INFECTIOUS DISEASES:  
IMPROVING R&D EFFICIENCY**

**Chair:** *Octavi QUINTANA-TRIAS*, Director, Directorate for Health, DG Research, European Commission, Belgium

*Solomon NWAKA*                      WHO/Special Programme for Research and Training in Tropical Diseases (TDR), Switzerland

*Ted BIANCO*                              Wellcome Trust, United Kingdom

*Bernard PÉCOUL*                      Drugs for Neglected Diseases Initiative, Switzerland

*Harvey BALE*                              International Federation of Pharmaceutical Manufacturers Association, Switzerland

*Robert SEBBAG*                      Sanofi-Aventis, France

*Joe FECZKO*                              Pfizer, United States

***Moderated roundtable discussion:*** New models of innovation – including PDPs, networks, and philanthropic R&D institutes – have the potential to increase the efficiency of the research and development cycle. Can existing strategies be scaled up or new models be piloted? This session examines opportunities to radically accelerate drug/vaccine/diagnostic development for infectious diseases.

- Is a new, more efficient innovation model emerging that will address the needs of small developing country health markets?
- How can we deliver a robust pipeline of new safe and effective products that meet required profiles for infectious diseases?
- How can we better exploit existing innovative drug development capacity in the OECD and encourage investment in such capacity in developing countries?
- What sorts of infrastructures and R&D are required to support new more efficient innovation models?
- How could the prioritisation, coordination or networking of R&D activities in infectious diseases accelerate drug/vaccine/diagnostic development?



***Other Organisations***

African Union	<i>Bience GAWANAS</i> , Commissioner, Social Affairs
European and Developing Countries Clinical Trials Partnerships	<i>Pascoal MOCUMBI</i> , High Representative, Ex-Prime Minister of the Republic of Mozambique

This high-level governmental session will comment on the proposed “Noordwijk Medicines Agenda”. Participants will discuss how to build political support for a strategy to improve the availability of drugs/vaccines/diagnostics for neglected diseases and the challenges to building policy coherence.

- Why do OECD countries have economic interests in addressing poverty related diseases that predominately affect developing countries?
- Should there be a global strategy to accelerate research and development in infectious diseases that primarily affect developing countries? How can countries contribute to it?
- How can we mobilize resources for investment in R&D for infectious diseases?
- How can we make sure that new drugs/vaccines/diagnostics are appropriate and affordable?
- How do we bridge the solutions for making products “available” with the solutions to keeping them “affordable”?

**16:15–16:45**

**COFFEE BREAK – IMPERIAL BAR**

**16:15–16:45**

***Press Conference – Windsor Salon***

**16:45–17:30**

**CONCLUDING REMARKS**

*Ab KLINK*, Minister of Health, Welfare and Sport, The Netherlands

*Bert KOENDERS*, Minister for Development Co-operation, The Netherlands

*Anarfi ASAMOA-BAAH*, WHO Deputy Director General

*Angel GURRÍA*, OECD Secretary-General

***Closure of the Forum***



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