

**OECD HIGH LEVEL FORUM ON POLICY COHERENCE:
AVAILABILITY OF MEDICINES FOR NEGLECTED AND
EMERGING INFECTIOUS DISEASES**

ISSUES FOR DISCUSSION

INTRODUCTION

This paper provides background information and raises issues for consideration by participants in the OECD High Level Forum (HLF) on Policy Coherence: Availability of Medicines for Neglected and Emerging Infectious Diseases.¹

What is the problem?

Infectious diseases are one of the primary causes of mortality in the world and in developing countries they are a major barrier to economic development, social progress and human health. An estimated 10.8 million people died from infectious diseases in 2001 and 10.6 million of those occurred in the developing world, while only 1.4 percent (150,000) occurred in high-income countries. The top four killers in Sub-Saharan Africa are infectious diseases, and the fifth is prenatal deaths. Those most vulnerable are children, pregnant women, young mothers and people in what should be their most productive years.

However, the health innovation system is failing to deliver new medicines, vaccines and diagnostics for neglected infectious diseases. These diseases include tuberculosis and malaria, but also tropical diseases such as Human African trypanosomiasis, leishmaniasis, schistosomiasis, Chagas disease, lymphatic filariasis and onchocerciasis.

To date, most medicines used to deal with such diseases in developing countries were first developed for other markets or purposes. Problems arise related to cost, safety, stability, formulation and resistance.

Mechanisms for addressing the lack of viable markets, expanding the global capacity for drug discovery, and increasing the productivity of R&D have to be found.

What can we do?

The Forum will focus on how to create co-operation, collaboration and coherent policies required to improve the incentives and efficiency of the innovation system to scale-up research and discovery.

Some new models of research and development which include partnerships, networks, and consortia are emerging – these need to be built upon.

Innovation is needed throughout the product cycle, from basic research through to delivery to the patient. Access must be regarded as an essential part of a functioning product cycle and support should be strengthened for reform of health systems at country level.

The HLF brings together Ministers, senior members of governments, industry leaders, philanthropies, international organisations, non-governmental organisations and academics to build support for an Agenda to create the cooperation, collaboration and coherence necessary for scaling-up availability.

What is the Noordwijk Medicines Agenda?

The outcome of the Forum will be the Noordwijk Medicines Agenda, which will identify opportunities for further OECD-wide action on how to stimulate innovation and radically accelerate the development and delivery of medicines, vaccines and diagnostics for neglected and emerging infectious diseases. It will suggest how a coherent policy environment could enable a health innovation strategy that is more efficient and reactive to global public health needs. The Noordwijk Medicines Agenda could feed into a process of international policy deliberations at OECD and WHO over the coming months.

POLICY CONTEXT

Over the last century healthcare innovation has transformed the way medicine is practiced and has brought substantial benefits in the prevention, diagnosis and treatment of diseases. But the problem of infectious diseases in developing countries has not equally benefited from innovative activity.

Increasing the availability and accessibility of medicines, vaccines and diagnostics for diseases that primarily affect developing countries has become the subject of heightened international attention over the past decade due to a number of factors including:

- The UN Millennium Development Goals (MDGs)². The High Level Forum in part responds to one of these targets: “In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries”.
- The involvement of philanthropic institutions that have made infectious diseases their focus.
- New initiatives that have improved research and development on neglected infectious diseases, including: the establishment of a number of Public-Private Product Development Partnerships, private sector philanthropic initiatives, and policy instruments like the Advanced Market Commitment Pilot.

The health sector is particularly challenging to development co-operation because of the large number and diverse nature of its development partners. Indeed, because the health sector illustrates many of the problems associated with ineffective provision of aid, it has been identified as a “tracer sector” for implementing the *Paris Declaration on Aid Effectiveness*, which was endorsed by over 100 Ministers, Head of agencies and other senior officials. The donor countries need to enhance harmonisation and alignment to partner country priorities for improved development outcomes in the health sector.

Meanwhile, the efficiency and productivity of innovation needs to be improved: a move towards a more open and collaborative model offers substantial opportunity for progress and for overcoming systemic failure.

To improve availability, a number of policy areas need to be brought together in a coherent manner including health, trade, science and technology, development co-operation and finance, in such a way as to create an environment that will spur both investments in, and efficiency of, research and product development. In turn, the availability of appropriate new health technologies could increase the effectiveness of development efforts for health.

For these reasons, the High Level Forum explicitly brings together the innovation, development and health communities in the hopes of developing a common agenda to increase the overall scale of R&D financing and the effectiveness of R&D activities for the diseases of the poor.

SESSION 1: THE ECONOMICS OF FIGHTING INFECTIOUS DISEASES

Participants are invited to consider the interests that could motivate OECD countries to increase their efforts to combat neglected and emerging infectious diseases. Economic arguments about the costs of inaction might be contrasted with the benefits of new approaches to developing health technologies. Participants might identify the scale of the R&D endeavour necessary and how the costs might be borne.

Traditionally the health and development communities have invoked humanitarian, developmental and ethical reasons for fighting infectious diseases. These motivations remain essential. In poor countries neglected infectious diseases impose heavy socio-economic costs:

- **Health** – Globally one in six people currently suffer from a neglected tropical disease. About half of communicable disease deaths take place in Sub-Saharan Africa.
- **Economy** – The annual costs of malaria in Africa have been estimated at a minimum of USD 12 billion; this resurgent disease alone may retard future African economic growth by 1.3 percentage points per year.
- **Society** – Disease impacts include lower physical endurance, loss of schooling, increased dropout rates, reduced investment incentives and postponement of the demographic transition.
- **Security** – As epidemics increase, large-scale migration exacerbates the situation in fragile states, as well as increases the possibilities of violent conflicts.

But it is not just poor countries that suffer. Severe Acute Respiratory Syndrome (SARS), which was first detected in Southern China and spread within five months to 28 countries, with an estimated USD 10-30 billion in costs. A global influenza pandemic could make such costs seem to pale into relative insignificance.

Meanwhile, a new infectious disease emerges every eight months and drug resistance has become a serious problem. There are ample reasons to believe that emerging infectious diseases will occur with increasing frequency and importance, with expansions in global population, travel, climate change and geopolitical threats.

Increasing the availability of new health technologies can help avoid some of these costs but there can be direct benefits too.

The policies and practices that are being put in place to address innovation failures for neglected and emerging infectious diseases could yield lessons relevant to health innovation generally. Creating efficiencies in the innovation cycle is key to quickly delivering new medicines to market at reduced costs.

- ***Could the applicability of more open or networked innovation structures, such as those used by Product Development Partnerships (PDPs), be broadened for the major non-communicable diseases of the wealthier countries too, where markets for medicines are likely to become increasingly fragmented due to genomics and targeted therapies?***

In considering this, clarity is required about the costs of scaling up R&D investments which needs to be accompanied by more accurate forecasting of demand. Better forecasting of the demand for medicines, vaccines and diagnostics required for neglected diseases, could reduce the risks to investors and potential innovators and could create stronger incentives to service these markets.

ISSUES FOR DISCUSSION

- ***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?***

SESSION 2: CREATING INCENTIVES FOR R&D INVESTMENTS: THE POLICY OPTIONS

New Policy mechanisms have recently been used to incentivise R&D in neglected infectious diseases. Participants are invited to consider the policy options and instruments presently available; their effectiveness; the gaps that remain and what new mechanisms might be envisaged to address these.

In recent years a number of policy mechanisms have been introduced to spur innovation. These policy mechanisms include both ‘push’ and ‘pull’ mechanisms.

Push mechanisms provide incentives for direct research inputs, usually at the front end of the innovation cycle. They focus on encouraging research generally rather than on delivery of specific end products and include: basic research funding, targeted R&D funds, Product Development Public-Private Partnerships (PDPs), and tax credits.

Pull mechanisms are designed to provide incentives for development and manufacture of useable technologies at the tail end of the innovation cycle. They motivate the development of products and are most effective when there are clear technological pathways. They are effective in generating a wide variety of discovery efforts in a competitive process, *e.g.* advance market commitments (AMCs), patent extensions, prizes, and patent buyouts.³

The push and pull mechanisms being experimented with to bring new health technologies onto the market are complementary, not competing, models.

Push and pull policy mechanisms do little, however, to create efficiencies in the innovation cycle.

There is a need for incentives all through the innovation cycle, from research to product delivery.

- ***What are the gaps or roadblocks in the health innovation cycle left unaddressed by the existing menu of mechanisms, (e.g. development of new leads, clinical trials)?***

Questions remain too as to when different mechanisms are appropriate; what mix of mechanisms might be necessary for certain diseases; and how to evaluate their effectiveness.

Metrics will become vital if we are to move away from a pure *pro bono* model of donation of drugs and funds and into alternate financing models that will need to attract funding based on clear measurable outcomes.

The criteria of success could include: health value or impact for developing country patients (including safety, efficacy, suitability, affordability, level of innovation); and drug development efficiency (including capacity, portfolios, development time, cost and cost-efficiency).⁴

- ***Which, if any, of these criteria seem the most promising for evaluation?***

Most of the PDPs and other mechanisms rely heavily on philanthropy and public funds, both of which could be subject to shifting priorities. As such, these mechanisms face uncertain financial futures.

In recent years a number of new and innovative funding mechanisms have been put forward or implemented to help generate more sustainable resources for development. These include Currency Transaction Development Levy (CTDL), Airline Tax; the International Finance Facility (IFF), the Healthcare Funding Framework (HFF), and the securitisation of financing for clinical trials.

- ***Can countries ensure adequate financing of the policy mechanisms to incentivise R&D?***

And finally, in order to build R&D capacity globally, developing countries need to be involved from the start. Partnerships and networking are important tools for building developing country capacity, and thus enhancing health surveillance, sharing knowledge and accelerating research and development.

Ultimately, developing countries should be able to research, develop and bring to market health technologies for diseases which are endemic in their own or other developing countries.

- ***Which of these policy mechanisms is successful in both engaging developing country participants and transferring knowledge and skills? Can we envision a for-profit model of medicine development for neglected infectious diseases that relies on developing world capacity?***

ADDITIONAL ISSUES FOR DISCUSSION

- *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?*

SESSION 3: NEW DRUGS FOR INFECTIOUS DISEASES: IMPROVING R&D EFFICIENCY

In this session participants are asked to consider more specifically; what are the needs- technical, financial, organisational or regulatory – to scale up research capacity in neglected and emerging infectious diseases? Can we improve R&D efficiency and/or reduce R&D costs? Can we expand on or better enable existing models for R&D? Can we better tap underused capacity and engage new actors to contribute capital, skills, infrastructures, know-how?

The cost of discovering a new drug candidate for each of the nine WHO priority tropical diseases could be of the order of USD 1 billion prior to clinical trials.

A transformation of the supply side in drug development is needed to lower these costs.

New models of innovation with the potential to increase R&D efficiency are under experimentation.

These employ more open strategies as well as mechanisms for collaboration that draw on global networks of researchers and other partners who often are connected virtually to discover new drug leads.

Such models aim to leverage both industry and public sector expertise and infrastructure and may involve partners in developing countries, thus expanding drug development capacity globally.

Creating such new and more efficient models has the potential to deliver beneficial spill-overs to the innovation models for wealthier nations too – as more and more rational design of medicines fragments markets.

We need to identify which mechanisms or which aspects of the existing models work best to feed the pipeline of health products for infectious diseases and then expand and improve on such approaches.

- ***How could these R&D models better:***
 - ***Prioritise research and align global efforts?***
 - ***Access industry skills and infrastructures?***
 - ***Better tap global R&D capacity?***
 - ***Exploit economies of scale in common infrastructures, platforms and knowledge sharing?***

A global, virtual collaborative drug discovery network which could act as a clearinghouse for existing initiatives and technology networks has been suggested.

It might increase the number of researchers involved in R&D for infectious diseases, their efficiency and their innovative output. Governments have a role in building international political support and creating policy coherence⁵.

- ***Should governments be involved and what are the policy measures that could facilitate scale-up?***

ISSUES FOR DISCUSSION

- ***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?***

SESSION 4: BUILDING POLITICAL SUPPORT FOR A WAY FORWARD: THE NOORDWIJK MEDICINES AGENDA

Participants are asked to comment on the proposed “Noordwijk Medicines Agenda”. High level government officials will discuss how to build political support for a strategy to improve the availability of drugs, vaccines, and diagnostics for neglected diseases and address the challenges to building policy coherence.

The challenge is to unite to a common mission and jointly mobilise the resources, human capital and intellectual assets in innovative ways to achieve the triple goals of accelerating innovation in neglected infectious diseases, improving health and reducing poverty.

Developing countries have to be involved from the onset and their views on innovation priorities fully taken into account in order to ensure that initiatives are aligned to their priorities as agreed in the principles of the *Paris Declaration on Aid Effectiveness*.

The draft Noordwijk Medicines Agenda puts forward some suggestions on how to intensify collaborative efforts and how we can better fund, organise, network and incentivise R&D activities in neglected and emerging infectious diseases.

ISSUES FOR DISCUSSION

- ***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”?***

ENDNOTES:

- ¹ Background for the High Level Forum came from 3 papers commissioned by the OECD: Sachs, J and Ehrlich Sachs S.(2006) “The Basic Economics of Scaling Up Health Care in Low-Income Settings”, Sachs J,(2007) “Improving Access to Essential Medicines in Low-Income Countries” and Kremer, M. and Williams, H. (2006). “OECD Country Policy Options for Increasing the Availability of Medicines for Neglected Diseases,”
- ² Three of the eight MDGs focuss on health – Reduce child mortality; Improve maternal health, and Combat HIV/AIDS, malaria and other diseases. Three of the others – Eradicate extreme poverty and hunger, Ensure environmental sustainability, and Develop a global partnership for development – have health targets and indicators. The High Level Forum responds directly to one of these targets: “In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries”.
- ³ Kremer, M. and Williams, H. (2006). “OECD Country Policy Options for Increasing the Availability of Medicines for Neglected Diseases”, Background paper prepared for the OECD
- ⁴ Moran et al. (2005). *The New Landscape for Neglected Diseases Drug Development*. The Wellcome Trust.
- ⁵ For R&D to be effective and for new medicines to benefit people in developing countries, OECD country policies also need to be coherent:
 - At national level – the R&D cycle needs to be embedded in a policy environment that includes sustainable poverty reduction, favours innovation and knowledge sharing, promotes quality standards and ensures effective surveillance.
 - Through *whole of government* approaches – the design of policy instruments available to OECD countries should be consistent with their health development objectives.
 - Between donors – avoid aid fragmentation currently caused by a plethora of disconnected health operations
 - With the priorities of developing countries – *alignment* of policies with developing country needs is fundamental, as is policy *ownership* by developing countries.