

Noordwijk Medicines Agenda

Noordwijk-aan-Zee, Netherlands, 21 June 2007

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. The HLF sought to build on and complement international momentum to 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. Participants made it clear that many health issues in developing countries cannot and will not be solved by developments in health technologies alone. Nevertheless, such technologies are important and efforts to accelerate innovation and to reduce poverty and its consequences must go hand and hand.

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.