# THE PATH TO NEW MEDICINES

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**Annotation:** The top priority in overhauling the innovation system has to be the delivery of medicines for infectious diseases to the poor. Governments can and should use this opportunity to drive a health-innovation strategy that is more efficient and reactive to global public-health needs — one that will leave our innovation systems in better health to deal more effectively with the challenges.

**Keywords**The goal of medical education is to transform the student from practitioner to healer. Medical education reform has produced significant movement from a process-driven approach, with a focus on defining requirements by time, to an outcomes-driven model, with a focus on defining relevant competencies and selecting the experiences that help learners achieve them. As part of this reform, a topic of rich discussion has been the time allocated to medical school, particularly the fourth year. There is growing recognition by students and faculty of the limited value of a senior year focused on the National Resident Matching Program ("the Match") as the predominant driver of content, with its random collection of "audition rotations." That said, we acknowledge that each year, the Match grows more stressful as medical schools expand. The goal of medical education is to transform the student from practitioner to healer. Medical education reform has produced significant movement from a process-driven approach, with a focus on defining requirements by time, to an outcomes-driven model, with a focus on defining relevant competencies and selecting the experiences that help learners achieve them. As part of this reform, a topic of rich discussion has been the time allocated to medical school, particularly the fourth year. There is growing recognition by students and faculty of the limited value of a senior year focused on the National Resident Matching Program ("the Match") as the predominant driver of content, with its random collection of "audition rotations." That said, we acknowledge that each year, the Match grows more stressful as medical schools expand.

**Over the next decade, it should be possible to produce a new generation of safe, effective and inexpensive medicines for many of the infectious diseases that afflict the poor. To achieve this, it will first be necessary to address the lack of viable commercial markets, to scale up the global capacity for research and**

**development (R&D), and to build a more efficient and more open mechanism for the discovery of new drugs. Governments can provide the leadership necessary to align the increasingly political issue of global health with philanthropic funding, technological capability and the new opportunities stemming from scientific progress. These are all increasing steadily and now is the time for governments to act.**

In June the Organisation for Economic Co-operation and Development (OECD) held a high-level forum on neglected and emerging infectious diseases in Noordwijk, the Netherlands. It brought together senior representatives from government, industry and academia and from philanthropic, international and non-governmental organizations. They discussed how to build strong international support for accelerating the development and delivery of new medicines, vaccines and diagnostic tests for diseases that disproportionally affect developing countries. The consensus that emerged is summarized in the action points of the Noordwijk Medicines Agenda

Although participants made it clear that many health issues in developing countries will not be solved by new technologies alone, these will still be important for reducing poverty and its consequences. The forum called on governments to show political leadership by joining with industry, product-development partnerships (PDPs), investors, shareholders, and intergovernmental and non-governmental organizations to intensify the cooperation and collaborations that will improve access to new health technologies for infectious diseases.

**'Push' and 'pull' tools**

Several experiments that include 'push' and 'pull' mechanisms have been introduced since 2000 to spur innovation in the fight against infectious diseases. Push mechanisms increase investment in research at the start of the innovation pathway: for example, by subsidizing the costs incurred when developing products for unprofitable or unpredictable markets. The most promising new push mechanisms involve public–private PDPs, which optimize leads, select candidates and bring products through clinical trials. The dozen or so existing PDPs are mainly funded by philanthropic organizations. Other push tools include basic research funding, targeted R&D funds (such as the proposed Industry R&D Facilitation Pull mechanisms — such as advance market commitments (AMCs), patent extensions, prizes and patent buyouts — are designed to provide incentives for the development and manufacture of usable technologies towards the end of the innovation pathway. They motivate investment by guaranteeing a reward for the product after the completion of its development phase. Pull mechanisms are politically attractive because they address a specific need (for example, lack of a market), are outcome-oriented, and are bounded by time and expense. In theory, pull mechanisms should stimulate a wide variety of discovery efforts in a competitive process but are probably most appropriate when the

technological route is marked out. In early 2007, a pilot AMC for the development of a vaccine against pneumococcal disease was launched with a US$1.5-billion commitment by five nations and the Bill & Melinda Gates Foundation, and a malaria-vaccine AMC is being planned. These funds will subsidize the purchase of a vaccine when it has been developed and is in demand in developing countries.

Designed correctly, a combination of push and pull mechanisms — including subsidies and markets guarantees — could facilitate the development of new vaccines and drugs for neglected diseases. We still do not know what the optimal mix of these policies is likely to be. So it is crucial to establish appropriate metrics for evaluating performance, to understand how to tailor different incentives for a broad range of diseases and treatments.

**Open innovation networks**

To increase the number of industry and public laboratories involved globally in research into neglected infectious diseases and to maximize the effectiveness of their contributions, a more fundamental transformation of the innovation pathway is necessary. Fortunately, this transformation process has already begun.

Failures in the innovation system can impede the development of appropriate health technologies for the developing world. These can occur at the level of generating and optimizing leads, during the rational identification and selection of candidate drugs from existing compounds, and in the clinical trials used to test new drugs or regimens. In particular, upstream research and early 'proof of concept' work, which provide new leads and create a pipeline of possible new health products, are weak.

The PDPs overcome these barriers by outsourcing knowledge, compounds and tools. The Special Programme for Research and Training in Tropical Diseases (TDR) is one organization that is developing a virtual drug-discovery capacity by using a series of portfolio, screening and medicinal-chemistry networks.

A more open innovation and collaborative research environment would also increase the efficiency and lower the costs of developing new, safe and effective medicines, vaccines and diagnostics through virtual networks What is needed is a better balance between stimulating innovation and providing broader access to knowledge. There are several tools, such as clearing houses and patent pools, and organizational forms, such as networks and consortia, that would promote easier and more open access to elements such as knowledge, data and process innovation. The challenge is to apply these to the neglected infectious diseases. Specific proposals for doing so include creating a shared global portfolio of prioritized drug-discovery projects and a portal for shared drug-discovery tools; matching potential collaborators on a particular project; supplying privileged access to chemogenomics data; and developing common platforms of intellectual property and management-support services.

**Intellectual-property rights**

The term 'open' applied to innovation does not necessarily mean a freely available source and the absence of intellectual-property protection. The Noordwijk Medicines Agenda recognizes that the protection and use of intellectual-property rights are important for encouraging investment in R&D, but these might not be sufficient to stimulate innovation as far as the neglected and emerging infectious diseases are concerned. But to attract and expand industry participation in such open networks, intellectual-property rights will need to be respected but the norms could be modified within the network. The intellectual property generated by the virtual teams within an open network is likely to be protected as it is in any other public–private collaboration.

Ideally, standard collaboration agreements would facilitate the rapid formation of collaborative arrangements. One possibility is that intellectual-property rights for any successful drug candidates produced would be licensed or donated to the sponsoring PDPs at the start of the clinical-development programme, although rights could be retained for use in other indications. In short, the network model proposed here is 'open' in the sense that it facilitates broader access to, and use of, data, knowledge and inventions within a worldwide network of researchers, but it would function within the present intellectual-property regime.

**Broader innovation benefits**

The drug market for infectious diseases in the developing world is both a challenge and an opportunity for the pharmaceutical industry, PDPs and other stakeholders. Unattractive, low-margin markets can be fertile ground for sparking innovation. With lower revenue growth predicted across the pharmaceutical industry in the coming decade, cost containment is becoming an industry-wide problem.

The top priority in overhauling the innovation system has to be the delivery of medicines for infectious diseases to the poor.

There might be relatively little economic profit to be gained from the development and licensing of drug candidates for the neglected diseases themselves. But there is an economic opportunity in applying the lessons learned from low-cost drug discovery for developing-world diseases to the wider range of niche and segmented non-communicable-disease markets in the developed world. The operation of networks as an emerging model of drug discovery could be an important innovation in its own right.

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