A New Deal to Close the Gap in Health Innovation and Access

The rising costs of health technologies and the lack of new tools to tackle health problems like disease outbreaks and antimicrobial resistance is a growing problem. Catalyzing innovation, especially for rare diseases, diseases of the poor, and the development of new antibiotics has proven very difficult without market incentives.

The twin challenges of innovation and access constrain health outcomes and hinder social and economic development in rich and poor countries.

The Imbalance Between Human Rights, Intellectual Property Rights and Public Health Objectives is Leaving People Behind

An Innovation Burden

Investment in the research and development (R&D) of health technologies is often impeded by low profit margins. The market’s influence on innovation has meant that many of the world’s health needs remain unaddressed.

The public sector provides approximately two-thirds of R&D investment in diseases that heavily affect the poor (HIV, TB and Malaria). Yet the private sector only finances about 10% of research in these diseases.

In the last decade, only two new classes for antibiotics have come to market, despite the looming crisis of antimicrobial resistance (AMR).

Antimicrobial resistance – a crisis in waiting

- Antimicrobial resistance (AMR) is estimated to kill more than 700,000 people globally per year today.  
- If AMR is not addressed, 10 million people are expected to die annually because of drug resistance by 2050.  
- In the last 25 years virtually no new antibiotics have been developed.  
- A continued rise in antimicrobial resistance would lead to a global reduction of 2% - 3.5% in Gross Domestic Product (GDP) by 2050.  

Antimicrobial resistance – a crisis in waiting

Investments in research and development (2009/2010)

<table>
<thead>
<tr>
<th>Source</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private sector</td>
<td>$144 billion USD</td>
</tr>
<tr>
<td>Public sector</td>
<td>$72 billion USD</td>
</tr>
<tr>
<td>Non-profit sector</td>
<td>$24 billion USD</td>
</tr>
</tbody>
</table>

In the last decade, only two new classes for antibiotics have come to market, despite the looming crisis of antimicrobial resistance (AMR).
Investment in the research and development (R&D) of health technologies is often impeded by low profit margins. The market's influence on innovation has meant that many of the world's health needs remain unaddressed.

Respect and Strengthen the Legal Landscape

Free-trade agreements containing protections on health technologies often go beyond the minimum standards for IP protection. International agreements should be used to improve innovation and access, not hinder it.

- Governments should award patents only when genuine innovation has occurred.
- Governments must not undermine the use of TRIPS flexibilities with explicit or implicit threats.
- Member states should create an enabling environment for exporting medicines under compulsory license.
- WTO Secretariat should consider formal reports of wrongdoing during the Trade Policy Review of Members.
- Members should register complaints of political and economic pressure, and take punitive measures against offenders.
- Countries that use international agreements to promote access to health technologies should be protected; countries that use political and/or commercial pressure to undermine international agreements should face punitive measures.

Implement Additional Models for R&D Funding

Where there are no market incentives, the costs of R&D must be delinked from the end prices of health technologies so that the governments and companies that invest in innovation can be fairly rewarded, and at the same time, people who need medicines can access them at a fair price. By supplementing the existing market driven system with innovative finance mechanisms, we can increase investment in needed technologies.

Public-Private Partnerships and Product Development Partnerships (PDPs)

Sharing the resources and strengths of the private and public sectors can accelerate innovation and allow investments to be made in health technologies that may lack a clear market incentive.

Grants and Prizes

Upfront contributions can lower the risks of investing in health technologies for diseases that affect people with low purchasing power. Rewards for projects that have reached certain milestones can incentivize investments on more economically ambitious or ambiguous ventures.

An Access Burden

Essential medicines and health technologies that prevent and treat diseases remain out of reach for millions worldwide. Where innovation exists, access is often hindered by economic constraints, which leads to needless deaths or pushes entire families into poverty simply for accessing the health services they need.

400 million people lack health care, including access to medicines, vaccines, diagnostics and medical devices, of whom 300 million live in middle-income countries.

Of the 12 medicines approved in the US for various cancer treatments, 11 cost more than $100,000 USD per year.

The Secretary-General’s High-Level Panel Report on Access to Medicines Makes Recommendations to Remedy Policy Incoherencies

Respect and Strengthen the Legal Landscape

Free-trade agreements containing protections on health technologies often go beyond the minimum standards for IP protection. International agreements should be used to improve innovation and access, not hinder it.

- Governments should award patents only when genuine innovation has occurred.
- Governments must not undermine the use of TRIPS flexibilities with explicit or implicit threats.
- Member states should create an enabling environment for exporting medicines under compulsory license.
- WTO Secretariat should consider formal reports of wrongdoing during the Trade Policy Review of Members.
- Members should register complaints of political and economic pressure, and take punitive measures against offenders.
- Countries that use international agreements to promote access to health technologies should be protected; countries that use political and/or commercial pressure to undermine international agreements should face punitive measures.

Implement Additional Models for R&D Funding

Where there are no market incentives, the costs of R&D must be delinked from the end prices of health technologies so that the governments and companies that invest in innovation can be fairly rewarded, and at the same time, people who need medicines can access them at a fair price. By supplementing the existing market driven system with innovative finance mechanisms, we can increase investment in needed technologies.

Public-Private Partnerships and Product Development Partnerships (PDPs)

Sharing the resources and strengths of the private and public sectors can accelerate innovation and allow investments to be made in health technologies that may lack a clear market incentive.

Grants and Prizes

Upfront contributions can lower the risks of investing in health technologies for diseases that affect people with low purchasing power. Rewards for projects that have reached certain milestones can incentivize investments on more economically ambitious or ambiguous ventures.
Initiate a Transparency Paradigm Shift

To help ensure prices are fair, the costs of R&D, marketing, production and distribution, as well as the end prices of health technologies should be clear.

- Governments should require all manufacturers and distributors to disclose the costs of producing and dispensing their products.
- Private biomedical companies involved in innovation should report, as part of their annual reporting cycle, on actions they have taken that promote access to health technologies.
- Public R&D funders should require that all knowledge generated from such research be made freely and widely available.
- WHO should establish and maintain a database of prices of patented, generic and biosimilar medicines in countries where they are registered.

Increase Investment

Throughout history, investments in R&D have improved the health and lives of millions. We have made immeasurable progress, but there is still dire need for new and more accessible health technologies.

Balance Private and Public Investment

In wealthy countries, 60% of R&D investment is from the private sector and 40% is from public and non-profit sources. But for R&D for diseases that primarily affect the poor, the public sector provides two-thirds of the funding.

Increase Government Obligation

Only 11% of publically provided R&D money comes from low and middle income countries. It is imperative that governments increase their current levels of investment to enable their citizens to live healthy lives.

Create a Framework of Accountability

The incoherencies between the right to health, trade, intellectual property and public health objectives can only be resolved if stakeholders are held, and hold each other, responsible for the impact of their actions on access to health technologies.

- The UN Secretary-General should establish an independent review body tasked with assessing progress on health technology innovation and access.
- Governments should review national policies that affect access to health technologies in light of human rights obligations and make the results publically available.

The Way Forward

Achieving global goals, particularly Sustainable Development Goal 3, which emphasizes health and well-being for all, will require reconciling the need for greater investment in innovation, services, and medicines, with the high costs of health technologies that are currently burdening rich and poor countries alike.