UNITED NATIONS SECRETARY-GENERAL'S
HIGH-LEVEL PANEL ON
ACCESS TO MEDICINES

Frequently Asked Questions

Question 1: Why did the UN Secretary-General set up a High-Level Panel on Access to Medicines?

- The UN Secretary-General acknowledges the important strides made over the last 15 years in enhancing access to treatment globally. Despite this progress, challenges remain. HIV, TB, malaria and viral hepatitis continue to kill more than 5 million people every year worldwide.
- The major noncommunicable diseases – cardiovascular disease, cancers, chronic respiratory diseases and diabetes – account for over 60 percent of the more than 50 million deaths worldwide.
- There are challenges both in incentivizing innovation for diseases where there are insufficient market incentives as highlighted by the 2014-15 Ebola outbreak in West Africa, or as illustrated by the looming crisis of antimicrobial resistance. There are also challenges in facilitating treatment access for many communicable and noncommunicable diseases. The twin challenges of innovation and access constrain health outcomes and hinder social and economic development in rich and poor countries alike.
- Recognising the interdependence of health and development and in line with the 2030 Agenda for Sustainable Development, including the Sustainable Development Goals and in particular SDG 3 on ensuring good health and well-being, the Secretary-General convened an independent High-Level Panel on Access to Medicines.
    - SDG 3 includes specific targets on the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, and access to affordable essential medicines and vaccines.
- The High-Level Panel's main purpose was to review and assess proposals and recommend solutions to remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies, that is impeding access and the right to health for millions of people around the world.
- The views of this independent High-Level Panel do not necessarily represent the views of the Secretary-General and/or the United Nations.

Question 2: How were the panelists for the High-Level Panel appointed?

- The 15 members of the High-Level Panel were selected among a wide range of eminent and respected individuals with expert knowledge and understanding of human rights, trade, public health and legal issues associated with innovation and access to health technologies – ensuring geographic and gender balance. High-Level Panel members included innovators, leaders of the pharmaceutical industry, public health, human rights and international law experts, civil society and government.
- The High-Level Panel's Expert Advisory Group was comprised of experts who have made significant contributions in their fields, including in human rights, public health, international law, science, innovation, intellectual property and international economics.
- Please contact the Secretariat of the High-Level Panel if you have more specific questions in this regard (e-mail: tenu.avafia@undp.org).

Question 3: How do the objectives of this High-Level Panel differ from prior efforts made to improve innovation and access to health technologies?

- The High-Level Panel has acted as a forum for the diverse range of parties engaged in the issues of health technology innovation and access.
- Within this setting, the High-Level Panel was tasked with proposing solutions to address the misalignment of human rights, trade, intellectual property and public health objectives.
- The High-Level Panel's report identifies new approaches that could attract broad-based support and strengthen the global partnership for sustainable development in a way that truly leaves no one behind.

Question 4: What's the aim of the High-Level Panel report?

- The international community is already well aware of the extent and nature of the key challenges inhibiting greater innovation and access to health technologies. The final report looks to bridge the gaps and inconsistencies between frameworks for health technology innovation, international trade, human rights, and public health needs.
- The High-Level Panel's final report is a consensus document agreed to by all 15 members.

Question 5: How did the High-level Panel balance the challenge of increasing access to health technologies with the need to incentivize innovation to ensure the development of new health technologies?

- The composition of the High-Level Panel included individuals with extensive expertise in both the originator and generic health technology industry, people with expertise in public health, human rights and international law, civil society and government. This balance is reflected in the recommendations made in the report.

Question 6: Are these recommendations reflective of the wider debate?

- The High-Level Panel has held a series of briefings with governments, the private sector and civil society. It also made an open call and received 182 submissions from multiple stakeholders, all of which can be accessed on the High-Level Panel's website (www.unsgaccessmeds.org), as too can a number of papers written by various individual experts and institutions with a mandate on issues of health technology innovation and access. The conversation was enriched by new contributions at the global dialogues held in London and Johannesburg, both of which can be viewed in their entirety on the High-

Level Panel website as well. All this information was critical to informing the final report and recommendations.

Question 7: How does the report propose catalyzing innovation, while keepings costs down so health technologies are accessible?

- Governments must urgently increase their current levels of investment in health technology innovation to meet unmet needs.
- Governments should enter into negotiations for a binding Research & Development treaty that delinks the costs of innovation from the end prices of health technologies to catalyze innovation where existing mechanisms have failed to produce sufficient numbers of needed health technologies.
- There must be much greater transparency to ensure that the costs of research and development, production, marketing, and distribution, as well as the end prices of health technologies are clear to consumers and governments.
- Intellectual property rules sensitive to public health issues can help address the misalignment between profit-driven innovation models and public health priorities.
    - Voluntary licenses between right holders and third parties to facilitate market entry of more affordable health technologies have helped to lower treatment costs but remain exactly that: voluntary. Moreover, many middle-income countries, where the majority of the world's poor live, are excluded from the scope of these licenses.
    - TRIPS flexibilities can ensure that patents are only awarded for genuine innovation.
    - The ability to determine the terms upon which compulsory licenses are issued and other TRIPS flexibilities are utilized, allows governments to fulfill their human rights obligations by securing the availability and affordability of health technologies.

Question 8: What are the report's key messages and recommendations?

- The High-Level Panel concluded that a much greater effort by all stakeholders, but governments in particular, must be directed to supplementing the existing market driven system with innovative financing mechanisms that delink the costs of R&D from the end prices of health technologies. The key messages/recommendations are:

To catalyze more health technology innovation, new models of funding for research and development must be implemented.

- Due to a lack of sufficient market incentives, we have not seen an adequate level of innovation in health technologies (defined in the report as medicines, vaccines, diagnostics and medical devices) needed to address anti-microbial resistance or for a number of diseases of the poor (like tuberculosis and neglected tropical diseases) as well as rare diseases.
- It is imperative that governments increase their current levels of investment in health technology innovation to meet unmet needs.
- Governments, the biomedical industry, institutional funders of healthcare and civil society should test and implement new and additional models for financing and rewarding public health research and development to ensure affordable access to end products for unmet needs.
- The UN Secretary-General should initiate a process for governments to negotiate global agreements on the coordination, financing, and development of health technologies to complement existing innovation models, including a binding R&D Convention that delinks the costs of R&D from end prices to catalyze innovation where existing mechanisms have failed to produce sufficient numbers of needed health technologies.

- Initially, governments should form a working group to begin negotiating a Code of Principles for Biomedical R&D and report annually on their progress in negotiating and implementing the Code in preparation for negotiating the convention in the UN General Assembly.

It is imperative that the right of countries to use TRIPS flexibilities to promote access to health technologies be protected. Conversely, those countries that use political and/or commercial pressure to undermine or impede the use of international agreements to promote health technology access should face punitive measures.

- WTO Members must make full use of TRIPS flexibilities as reaffirmed by the Doha Declaration to promote access to health technologies when necessary. In particular they must:
  - Ensure patents are only awarded when genuine innovation has occurred
  - Enable the expedient use of compulsory licensing to increase access to health technologies
- Revise the paragraph 6 decision of the Doha Declaration in order to find a solution that enables swift and expedient export of medicines produced under compulsory license.
- Governments must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities. Instances of undue political and commercial pressure should be formally reported to the WTO Secretariat during the Trade Policy Review of Members. WTO Members must register complaints against undue political and economic pressure, and take punitive measures against offending Members.
- The report outlines two examples, in Thailand and Colombia, where this happened and the recommendation in the report propose that action be taken at the WTO to safeguard the rights reaffirmed in the Doha Declaration.

A paradigm shift in transparency is needed to ensure that the costs of R&D, production, marketing, and distribution, as well as the end prices of health technologies are clear to both governments and patients.

- Rich and poor countries alike are adversely affected by high prices being changed for health technologies. With the taxpayer effectively paying twice for health technologies in terms of R&D grants and/or tax breaks as well as the end costs for the technology, the report recommends a paradigm shift in transparency to ensure that the costs of health technology R&D, production, marketing and pricing.
- Governments should require manufacturers and distributors of health technologies to disclose the costs of R&D, production, marketing, and distribution of health technologies being procured or given market approval by health authorities and the details of any public funding received in the development of health technologies, including tax credits, subsidies, and grants.
- Biomedical private sector companies involved in health technology innovation and access should report, as part of their annual reporting cycle, on actions they have taken that promote access to health technologies.
  - The private sector should also develop publicly available policies on their contribution to improving access to health technologies, and establish a governance system that includes board-level responsibility and accountability for improving access to health technologies.

- Governments should require that the unidentified data on all completed and discontinued clinical trials be made publicly available in an easily searchable public register, regardless of whether the results are positive, negative, neutral or inconclusive. Those undertaking clinical trials must not prevent researchers from publishing their findings.
- Public funders of research must require that knowledge generated from such research be made freely and widely available through publication in peer-reviewed literature, and seek broad, online public access to such research.
- International organizations working in this area should cooperate with one another and with other relevant bodies to support governments to define public health-sensitive patentability criteria and to strengthen the capacity of patent examiners to apply rigorous public health-sensitive standards of patentability.
- WHO should establish and maintain an accessible international database of prices of patented and generic medicines and biosimilars in the private and public sectors of all countries where they are registered and where this information is available.

Question 9: How is it going to be possible to hold all stakeholders accountable on the recommendations made in this report?

- The incoherencies between the right to health, trade, intellectual property and public health objectives can only be resolved using robust and effective accountability frameworks that hold all stakeholders responsible for the impact of their actions on access to health technologies.
- Transparency is necessary to hold governments, the private sector and other stakeholders accountable for the impact of their actions on access to health technologies.
- Transparency is also necessary around the costs of R&D, marketing, production and distribution, as well as the end prices of health technologies, which are currently difficult to aggregate and complicate the task of holding governments and the private sector accountable for high prices.
- The absence of transparency in clinical trial data and the lack of coordination between national drug regulatory authorities also contributes to delays in the registration of new health technologies.
- Trade and investment agreements containing TRIPS-plus provisions are generally negotiated in secret. This lack of transparency makes it difficult to hold governments and other stakeholders accountable for the impact of their policies and actions on access to health technologies.
- The High-Level Panel's report makes a number of recommendations on strengthening governance and accountability for better innovation and access.

Question 10: Is the report an attack on intellectual property rights, which underpin patents. Is this the objective of the High-Level Panel?

- No, the report is not an attack on intellectual property system. In fact the opposite is true, at present the market is not innovating effectively to various challenges like antimicrobial resistance, diseases of the poor and rare diseases because there is not a clear immediate return on investment. The High-Level Panel's report make recommendations for improving the system so that there is move investment in innovation, innovation is sufficiently remunerated and rewarded and there is greater access for patients in need.

- The High-Level Panel acknowledged that there are many determinants of health technology innovation and access beyond intellectual property and that these require urgent attention. However, the High-Level Panel, based on its mandate it was given focused its report on the question of policy incoherence between the justifiable rights of inventors, trade rules, public health objectives and human rights.

Question 11: Is the High-Level Panel trying to undo Bayh-Dole's stated purpose, which was to enable and encourage the commercialization of federally-funded basic scientific research?

- No, the High-Level Panel is not trying to undo Bayh-Dole. In the 21st century, we are facing ever-increasing challenges and we need to find ways to increase collaboration on health technology innovation For example, at present because research is often not open to everyone, repetitive research is taking place, which is slowing down the development of new lifesaving medicines, vaccines and diagnostics.
- This High-Level Panel was committed from the start to looking at new ways to incentivize innovation and increase access to health technologies.

Question 12: What happens next?

- The key outcome of the High-Level Panel's work is an evidence-informed, rights-based analysis of contributions and recommendations to promote the development and production of health technologies in a way that balances trade, human rights and public health.
- The recommendations are anchored in the Sustainable Development Agenda's aspiration to leave no one behind, and in particular to ensure healthy lives and well-being for all (SDG 3). Everyone has a role to play in this worthwhile endeavor, and through their recommendations, the High-Level Panel call on all stakeholders to reinvigorate the debate and actions to ensure that health technologies are affordable and accessible for all.
- In the interests of transparency, the Secretary-General supports the High-Level Panel's wish to make this report publicly available.