HIGH-LEVEL PANEL ON ACCESS TO MEDICINES

2016: two striking reports:

United Nations Secretary-General's High-Level Panel on Access to Medicines;

Lancet Commission on Essential Medicines

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The 2030 Agenda for Sustainable Development

On 25 September 2015, 193 UN Member States unanimously adopted the 2030 Agenda for Sustainable Development, which emphasizes leaving no one behind

Methodology for the UNSG HLP

High-Level Panel to review and assess contributions for remedying the misalignment between intellectual property, trade, human rights and public health that impedes access to health technologies.

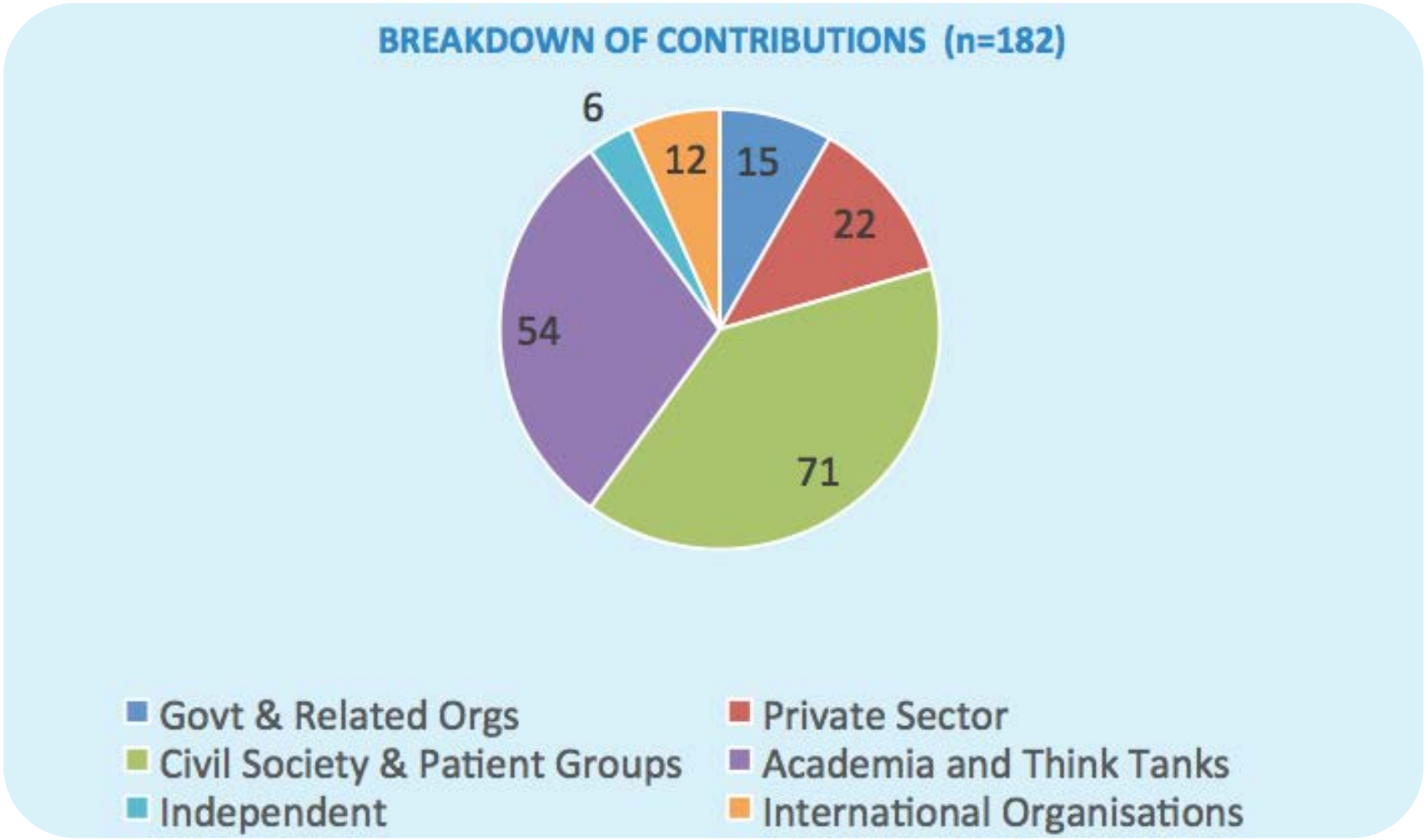
Global Dialogues to diversify multi-stakeholder inputs on the short-listed contributions selected by the High-Level Panel. Members of the High-Level Panel and the Expert Advisory Group will participate.

Expert Advisory Group to provide technical support to the High-Level Panel.

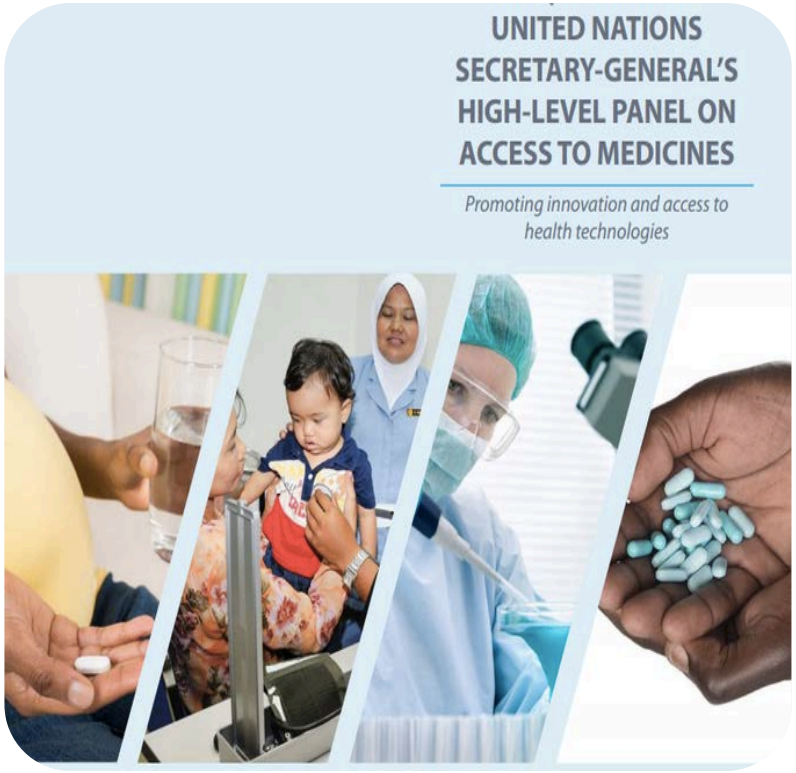
Regarding the process

- In line with the recommendations of the 'Global Commission on HIV and the Law', 2012
- In the context of the Post-2015 Agenda and the SDGs
- *"to review and assess proposals and recommend solutions for 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".*

Contributions



Report Released on 14 September 2016



- Health technology innovation and access
- Intellectual property laws and access to health technologies
- New incentives for health technology R&D
- Governance, accountability and transparency

Key Findings: Barriers to Accessing Treatment

- Access is a global issue, not restricted to LICs
- For hepatitis C, direct acting antivirals, such as Sofosbuvir, are successful in curing hepatitis C
- Sofosbuvir marketed at US$ 84K per patient in the United States
- Gilead signed 5 year voluntary licenses covering 112 lower middle-income countries
- 50 middle-income countries with 49 million people living with Hep C were not included in these licenses (43% of all people living with Hep C)
- 2.6 million people in Brazil, 1.5 million people in Thailand and 30 million people in China live with Hep C

Recommendations: IP and Access

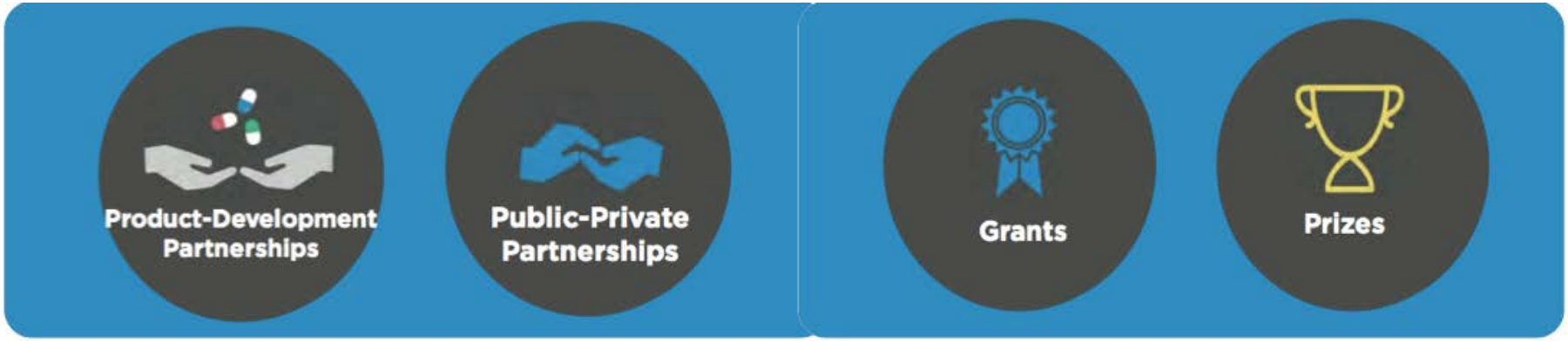
- WTO Members must make full use of policy space available in Article 27(1) of TRIPS to curtail ever-greening and reward genuine innovation
- Governments should adopt and implement legislation that facilitates the quick, fair and predictable issuance of compulsory licenses
- WTO Members must revise the paragraph 6 decision to find a solution that enables swift and expedient export of pharmaceutical products

Recommendations: IP and Access

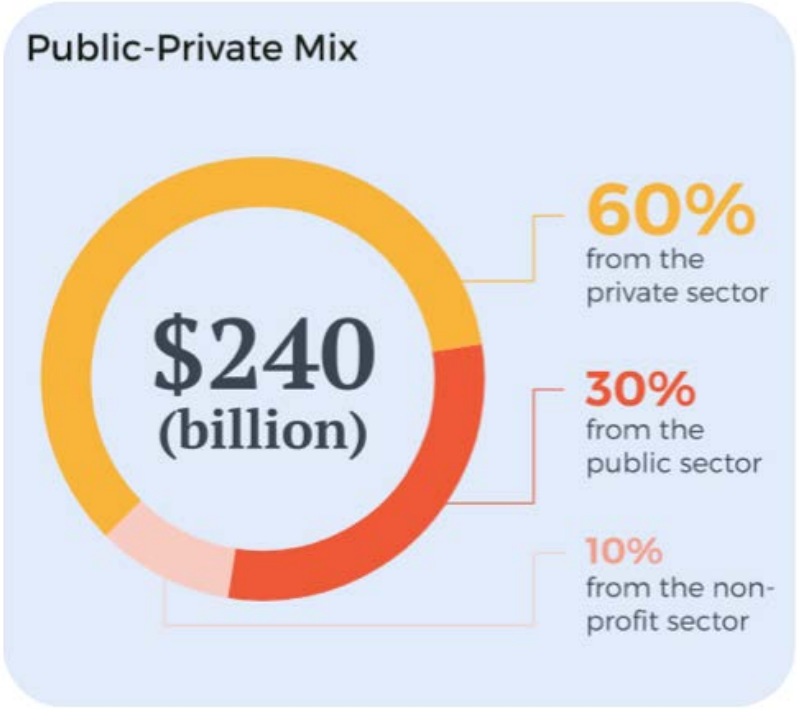
- Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities
- Governments involved in trade negotiations should not compromise right to health by adopting TRIPS plus measures
- Governments should undertake public health impact assessments before entering into trade and investment agreements

Recommendations: New Incentives for R&D

- Coordinated and collaborative efforts of public-private partnerships and product development partnerships have brought together the resources and strengths of the private, philanthropic and public sectors to innovate and deliver several important health technologies
- Innovative mechanisms to address unmet needs have enabled policymakers to invest according to public health priorities



Recommendations: Binding R&D Treaty



- The UN Secretary-General should initiate negotiations for a binding R&D Convention that delinks R&D costs from end prices
- As a preparatory step to negotiating the Convention, governments should implement a code of principles that would apply to public R&D funds and should be adopted by private and philanthropic funders, product development partnerships, universities, and the biomedical industry
- This recommendation was made to address the gridlock at WHO on a binding R&D treaty

HLP: our vision (personal) of what was missing

- Recognize that the current R&D and Access system has failed.
- Concrete and feasible proposals for the short, medium and long-term to remedy a failed system.
- To propose a new IP system for pharmaceuticals, consistent with international codes of human rights and public health, safeguarding the rights of the inventors or individual rights (reaffirming previous recommendations [Global Commission on HIV and the Law, 2012]).
- Countries must be free of pressures when using TRIPS flexibilities, including patenting criteria decisions (litigation of pharmaceutical companies against Argentina and Brasil)

HLP: our vision (personal) of what was missing

- TRIPS-plus on FTAs immediately halted, reverted and banned.
- Too much emphasis on Voluntary; much less on Compulsory measures.
- Essential medicines (WHO Model List for Essential Medicines) excluded from patent protection (Global Health Law Committee of the International Law Association: **effectively automatic compulsory licensing for essential medicines**).
- Extension of the "waiver" for the LDCs.
- Strengthening legal and advocacy roles of civil society.
- Further discussion of the Colombia case (Imatinib Novartis).

Next steps?

- Clarify and make public legal implications, consistency of proposals with the TRIPS Agreement and the “unintended consequences” of the proposed approach.
- Dialogue with WTO for making effective proposals.
- Maintain the debate high in all possible forums.
- Addressing regional approaches, local production capacity and linking with the Lancet Commission on Essential Medicines (expand the LC indicators to a global approach to cover issues raised on the HLP).