**Civil Society Input to the 1st World Conference on Access to Medical Products and International Laws for Trade and Health in the context of the 2030 Agenda for Sustainable Development that took place in Delhi, India in November 2017**

**We congratulate the organizers of the meeting, the India's Ministry of Health & Family Welfare with the support of the WHO Country Office for India and the Indian Society of International Law, for promoting a timely discussion about strategies to advance access to health technologies and new models for innovation, including the recommendations of the UN Secretary General High Level Panel on Access to Medicines, within the context of 2030 Agenda.**

**General Recommendation for the final outcome document report to:**

- Highlight that it is about people's right to access the fruits of biomedical research and to access health services: Patient needs.
- Acknowledge that inequality in access to medicines is unjust, unethical and unsustainable and contravene the fundamental human right to health and the Agenda 2030.
- Recognise high prices of medicines and other medical products and lack of patient-driven innovation, is now a global challenge - across the north and south - irrespective of the sophistication of the health system or the economic classification of countries. It is about all health technologies for all diseases for all people.
- Welcome the recommendations of the UN Secretary General High Level Panel on Access to Medicines and suggest appropriate follow at domestic, regional and global level, including upcoming 2018 WHO Executive Board and United Nations negotiations.
- Acknowledge the incoherence between public health, human rights and trade (including IP protection and enforcement) frameworks.
- The correct diagnosis and remedy of the incoherence should lead to designing effective, efficient and equitable solutions and correct any further harmful measures being pursued.
- Demand more accountability and public return in exchange for public investment into innovation by promoting new approaches to biomedical innovation that do not rely on exclusivity and high prices and de-link R&D costs from prices, as well as transparency of R&D investments, costs and outputs.

**Recommendations for Governments:**

1.Ensure coherence at the multilateral, regional and national levels so that all policies advances the right to health, the right to benefit from scientific progress, and in order to contribute to achieving the Sustainable Development Goals, including SDG 3s, including through formulation of interministerial bodies and strategies at the national level to increase access to medicines and innovation to health technologies;

2.Review existing intellectual property legislation and regulations impacting medical technologies and implement and adopt legislation as needed to maximize adoption, ease of use, and protection of all TRIPs flexibilities and other tools to ensure access to affordable medical technologies, including strict patentability criteria, compulsory licenses, patent oppositions and others, in light of the principles and provisions of the Doha Declaration, to meet the public health needs of medicines,

vaccines and other health technologies. After adoption, facilitate countries, private sector and civil society, use of such flexibilities as needed to address needed access to affordable health technologies.

3.Refrain from explicit or implicit threats or tactics that undermine the right of countries to use TRIPS flexibilities. To build political will to withstand pressure that undermines measures to encourage access to affordable medicines with the use of TRIPS flexibilities and principles of Doha Declaration

4.Report on the barriers to the operationalization and full use of the TRIPS flexibilities to ensure affordable medicines prices including pressure and threats from other countries.

5.Ensure that engagement in bilateral and regional trade and investment treaties do not include provisions that interfere with governments ability to regulate pharmaceutical prices, increase competition in pharmaceuticals and fulfil the right to health especially avoid TRIPS+ measures, ISDS, and IP enforcement norms on injunctions, damages and other remedies that reduce the flexibility in the TRIPS agreement, limit the availability of injunctions and implement royalty rules rather than exclusive rights.

6. Increase transparency and stakeholder participation during the negotiations of bilateral and multilateral trade agreements and undertake health impact assessment of proposed provisions that threaten the meeting of public health needs of the population and make these studies public.

7. Launch a high-level political process aimed at renegotiating how countries collectively coordinate,s et priorities and finance or incentivise R&D so that it satisfy the basic principles of the use of open knowledge innovation, access to clinical trial data, transparency, de-linkage of the final price from the R&D costs.

8. Form a Working Group to begin negotiating the operationalization and implementation of a Code of Principles for Biomedical R&D which should build on those principles already included in the WHO Global Strategy and Plan of Action on Public Health and WHO CEWG follow up. Member states would report annually in their progress negotiating and implementing the Code of Principles.

9.Ensure initiatives to finance or incentivise pharmaceutical innovation are designed in a way that contributes to a fairer, more effective and efficient biomedical innovation system better able to answer to public health and right to health needs, by ensuring the affordability of end products.

10. Implement measures that encourage and authorise governments and other public institutions such as universities to leverage investments into publicly-funded research in public interest.

11. Undertake measures to enhance the transparency of markets for all health technologies and collaborate with other governments and intergovernmental bodies to create minimum standards for transparency as regards information from the design, enrollment and outcomes from clinical trials, the subsidies and costs of research and development in sufficient detail for useful analysis, the landscape of R&D investments by disease, geographic area and entities performing R&D, and the licensing of intellectual property rights, the cost of production, marketing outlays and prices;

**Recommendations for WHO Director General:**

1.Propose the establishment of a UN level mechanism supported by WHO to assess policy coherence within the SDGs on current UN work programs, mandates and technical assistance as it relates to access to medicines and innovation on health technologies, and report back to Member States with a proposal for next steps in improving policy coherence.

2.Strengthen the technical support to member states to develop public health impact assessments of treaties on trade and investment, that measures the threat implied by having a commitment to such treaties on meeting the public health needs of their population using a human right and public health approach;

3.Develop and publish impact studies that document the public health and financial cost of applying TRIPs plus levels of IP protection on generic competition, innovation, affordability and access to medicines, and on the proportion of pharmaceutical in expenditure in health budgets.

4.Commission further studies that evaluate the feasibility and operability of practical and concrete approaches to financing R&D for biomedical innovation that eliminate the link between the expectation of high prices and the incentive to invest in R&D, so that goals regards innovation and access do not conflict with each other.

5.Provide the technical assistance to Member States to further work on public procurement programs that aims at enhancing the procurement of medicines based on the best procurement practices, enhancing the concept of informed decision, and increased transparency on pricing, on the inputs throughout the value chain of the production of medicines and its relevance to the end price.

6.Promote the adoption of new mechanisms to mobilize resources to build sustainable, coherent,solutions for financing of health research and development, to advance the right to health and the right to benefit from scientific progress. Such mechanisms should integrate public health safeguards, as summarized in WHA 66.22 in order to find solutions to the unmet medical needs which ensure a fair public return for public investments, and enable the delinking of R&D incentives from drug prices to that products are more affordable and access is more universal.

7. Facilitate, in its normative role, the creation and negotiation of a working group to begin negotiating a Code of Principles for Biomedical R&D and other R&D normative frameworks, which should build on those principles and strategies already included in the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and follow up resolutions to the WHO CEWG Report.

8.Creating an enabling environment and undertake measures to enhance the transparency of markets for diagnostics, medicines and vaccines, in every area where transparency improves policy making, research and the allocation of resources and empowers patients and taxpayers ensuring public return of R&D investments.

9.Collect and analyze data on health technologies of public health importance, including but not limited to:

a. Actual costs of R&D on specific medicines and vaccines, including the enrollment , and costs of each individual clinical trial. and
b. costs of individual clinical trials,
c. Actual manufacturing costs of specific drugs, vaccines and health technologies;
d. Manufacturing know-how,
e. The landscape of patents, including information about disputes about the validity
f. and/or relevance of asserted patents;
g. The terms of licenses to patents and other intellectual property rights.
h. The revenues from product sales and the licensing of intellectual property rights.

**Recommendations for UN Secretary General:**

1. Incorporate access to medicines and innovation strategies and reforms, including a discussion on the UN Secretary General High Level Panel on A2M recommendations, in relevant ongoing UNGA processes, including 2018 HLMs on NCDs and TB and follow up on AMR, HIV-AIDS and global health crisis processes.

2. Ensure the Agenda 2030 and SDGs strategies, specially on promoting universal health coverage, includes strategies to support countries efforts to increase access to affordable medicines, vaccines and health products and the promotion of patient-driven biomedical innovation.

3. Hold a UNGA special session on access and innovation to health technologies in 2018/2019 to allow for a global, comprehensive and systematic overview of the challenges and opportunities including all diseases, technologies and countries.

4. Create a UN interagency task force to promote policy coherence and UN-wide coordination on strategies that impact on access to medicines and innovation in the context of Agenda 2030 SDGs.

**Recommendations for Indian Government:**

1. Prioritise an increase and sustainable public financing for R&D that addresses key un-meet health needs including neglected diseases, antibiotic resistance, tuberculosis and emerging infectious and non communicable diseases. Introduce and fund incentive mechanisms that de-link the financing of research from health technologies sales and prices.

2. Make use of all the TRIPS flexibilities including strict patentability criteria and third party patent challenges at the examination stage and presumptive compulsory licenses to ensure access to affordable medicines.

3. Ensure that trade agreements with EU, US, Switzerland, Japan or any other country does not include TRIPS+ nor ISDS measures.

4. Secure transparency and participation of public interest groups in all trade agreements negotiations.

5. Collaborate with other governments to secure a UNGA special session on medicines in 2019.

6. Collaborate with other member states to mandate WHO to prepare for negotiations on a new global framework on R&D that prioritize the discovery, development and delivery of affordable innovations of public health importance. iPromote open source innovation to enhance effectiveness & efficiency of biomedical research.

7. Ensure transparency on cost of R&D for every clinical trial that is publicly funded, and the unredacted text of all licenses to patents based upon government funded research.