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Report of the Side Event of the Seventieth World Health Assembly

on

Impact of the Recommendations of United Nations Secretary-General's High-Level Panel on Access to Medicines in the Context of the 2030 Agenda for Sustainable Development

24 May 2017

Supporting Organizations:



UN SG's High-Level Panel On Access To Medicines



Partners in Population and
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Preface

The Seventieth World Health Assembly (WHA) side event on ‘Impact of the recommendations of the United Nations Secretary-General’s High-Level Panel on Access to Medicines in the context of the 2030 Agenda for Sustainable Development’ was held on 24 May 2017 at Palais des Nations, Geneva, Switzerland.

The 2030 Agenda for Sustainable Development (2030 Agenda, SDGs) adopted in 2015 by 193 Member States of the United Nations highlighted the need to expand access to medicines and health products in the SDGs, more specifically in SDG 3 and many other SDG targets. Access to health products will be the key for countries to progress towards Universal Health Coverage (UHC).

This side event was sponsored by several World Health Organization (WHO) Member States for whom the issue of access to medicines and the implementation of the United Nations High-Level Panel (UNHLP) recommendations are very important. Partners in Population and Development (PPD) facilitated this event. The key purpose of this event was to hear the experiences of countries who are using mechanisms, notably those recommended by the UNHLP, that support access to medicines, as well as other initiatives such as price control and local production.

The Director General of WHO, Dr Tedros Adhanom Ghebreyesus has committed to work towards UHC. He has reaffirmed the priority for WHO to improve access to essential medicines for all.

The audience was invited to support and endorse a Joint Declaration prepared by the sponsors to increase the momentum for adoption of the UNHLP recommendations by WHO, including the United Nations General Assembly (UNGA) special session convened no later than 2018, to agree on strategies and an accountability framework that will accelerate efforts towards promoting health technology innovation and ensure access; and strengthen South-South Cooperation among Member States to share initiatives and lessons learned on access to medicines. The text of the Joint Declaration is available at <http://partners-popdev.org/wha-may2017/>

This side event has been possible and successful only because of the inspiring leadership of the sponsoring countries and total cooperation of the supporting organizations. Thank you to the core team of organizers who from the very beginning ensured a successful event.

- Mr. Khalid Atlasi, Permanent Mission of the Kingdom of Morocco, Geneva, Switzerland
- Mr. Fernando Rosales, Permanent Mission of the Plurinational State of Bolivia, Geneva, Switzerland
- Dr. Sumit Seth, Permanent Mission of the Republic of India, Geneva, Switzerland
- Mr. Twaha Matata, Permanent Mission of the Republic of Uganda, Geneva, Switzerland
- Mr. Jackson Galindo, Permanent Mission of the Bolivarian Republic of Venezuela, Geneva, Switzerland
- Mr. Tenu Avafia, The United Nations Development Programme (UNDP)
- Ms. Viviana Tellez Muñoz, South Centre
- Ms. Vibhu Garg, Partners in Population and Development
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Agenda of the Side Event of the Seventieth World Health Assembly

on

Impact of Recommendations of United Nations Secretary-General's High-Level Panel on Access to Medicines in the Context of the 2030 Agenda for Sustainable Development

24 May 2017

18:00–19:30hrs, Room VII, Palais des Nations, Geneva

Introduction – 5 mins

Interventions – 5 mins each

1. *High-Level Panel on Access to Medicines in the context of the 2030 SDGs.* **Co-Chair of the UNHLP; former President of the Swiss Confederation**
2. *Local manufacturing: an opportunity for addressing the needs of vulnerable groups at an affordable cost.* **Minister of Health, Morocco**
3. *India's experience in improving access to affordable treatment.* **Minister of Health and Family Welfare, India**
4. *Enhance accessibility of healthcare in the context of promotion and protection of traditional medicines.* **Minister of Health, Bolivia**
5. *WTO's temporary waiver until 2033 – Experience from an LDC.* **Minister of Health, Uganda**
6. *Price controls for essential drugs: do they protect the poor and vulnerable?* **Minister of Health, Venezuela**
7. *Role of policy coherence in fostering health technology innovation and access.* **Director, UNDP Geneva**
8. *Implementation of the HLP recommendations.* **Special Adviser for Health, South Centre**
9. *Role of partnerships and South-South Cooperation.* **Executive Director, Partners in Population and Development (PPD)**

Interactive Discussion, Conclusion and Adoption of Joint Declaration – 30 mins

Moderator: **Dr. Denis Broun**, Member of the UNHLP Expert Advisory Group; Permanent Observer of PPD to the UN Office and other international organizations in Geneva.

Summary of Interventions from the Panel



Ms. Ruth Dreifuss, Co-Chair of the United Nations Secretary-General's High-Level Panel on Access to Medicines described the UNHLP recommendations as a toolbox of measures and policies supporting the implementation of health-related goals and targets of the 2030 agenda for sustainable development. She noted that while some goals have been reached in recent years due to public private partnerships, e.g., in the areas of research and development, availability of medicines, vaccines, diagnostics and medical devices, many serious gaps remained, with communicable and non-communicable diseases causing more deaths each year worldwide. Medicines to treat

diseases as diverse as hepatitis C, cancer, cystic fibrosis or dengue remained largely unavailable or inaccessible to many. She pointed out that this issue not only affects low and middle-income, but also high-income countries.

She characterized the work of the UNHLP as broad – resolved to address all diseases, all health technologies and all countries in line with the 2030 agenda – yet narrow – focussing on “the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”

The High-Level Panel in its report is clear that trade and intellectual property barriers are not the sole reason why people do not get the healthcare they need. Other reasons include: under-resourced health systems, a lack of sufficiently qualified and skilled healthcare workers, inequalities between and within countries, exclusion, stigma, discrimination and exclusive marketing rights, to name some. The Doha Declaration was an important effort of balancing health priorities and trade laws. 15 years later, with progress having been made, backlashes have also accrued.

Ms. Dreifuss’ reiterated the key calls to action from the report:

- Governments must increase current levels of investment in health technology innovation to meet unmet needs. Public funders of research must make it unconditional that knowledge generated from such research be made freely and widely available through publications in peer-reviewed literature, and seek broad, online public access to it.
- Governments must enter into negotiations for a binding Research & Development treaty that delinks the costs of innovation from the end prices of health technologies;
- There must be greater transparency to governments and consumers in terms of costs of research and development, production, marketing, and distribution, as well as the end prices of health technologies;

- WHO should establish and maintain a database of prices of patented, generic and biosimilar medicines in countries where they are registered;
- UN Member States should convene a High-Level meeting on Health Technology Innovation and Access.

She concluded by calling for increasing innovation for unmet health needs and making access to health affordable. The right to health obliges countries and stakeholders to act now, and act together – lives are at stake.

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Dr. Hicham el Berri, on behalf of the Minister of Health, Kingdom of Morocco explained that the topic was at the heart of his country's priorities. Morocco put in place a national pharmaceutical policy in line with the WHO guidance to reform its pharmaceutical sector. These efforts have resulted in a reduction of prices for drugs and vaccines. 2000 medicines have seen their prices decreased by 20 to 80 per cent, thanks to encouraging greater transparency. Generics for hepatitis C are today available for US\$300 per month (or US\$900 for a full three-month treatment), whereas the originator's product was marketed at over US\$80000. Thanks to a vibrant local production capacity, two manufacturers produce Sofosbuvir in Morocco, since there is no patent registered in the country. This has had an important impact on the price, and enabled the country to fully reimburse the treatment of hepatitis C through the national health insurance system. Dr. el Berri encouraged other African countries to foster exchanges of knowledge and know-how.

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H.E. Mr. J. P. Nadda, Minister of Health and Family Welfare, India stated that access to medicines was critical for realizing the 2030 sustainable development agenda. He encouraged the use of TRIPS flexibilities and investment in research and development. He drew the attendees' attention to India's 2017 National Health Policy and its pivotal role in providing access to medicines worldwide.

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The Minister also stated that 59% of the WHO prequalified Active Pharmaceutical products are from Indian manufacturers. India is a leading provider of the generic antiretroviral therapy through the WHO prequalification program. India is also supplying vaccines to nearly 150 countries and agencies, including UNICEF, WHO and Pan American Health Organization (PAHO) through its 21 major vaccine manufacturing facilities. He described the Government's "Make in India" campaign to further push for making it a hub for manufacturing affordable medical devices and similar biologics.

He stated a renewed focus on quality and rational use of medicines and a comprehensive action plan involving all relevant departments have also been prepared for addressing concerns relating to Antimicrobial Resistance (AMR). India is investing US\$275 million for strengthening its National Regulatory Authority and its competencies have been acknowledged through a comprehensive review with the WHO Global Benchmarking Tool in February, 2017. The Pharmacovigilance Programme of India has now 245 Adverse Drug Reaction Monitoring Centres.

Free drug and diagnostic facilities are being extended in all States to enhance access. India continues to support the formation of the South-East Asia Regulatory Network for ensuring access to high-quality medical products in the region. He supported the findings of the UNHLP and called for coordination, financing and development to complement existing innovation models to fund research and development. The Minister expressed the possibility for WHO, in consultation with all stakeholders, to play a crucial role in enhancing both innovation and access, including prices of new pharmaceuticals and rapidly changing requirements for health technologies. He stressed the importance of evolving strategies and an accountability framework that accelerates this. He concluded by saying that India would be happy to engage with all stakeholders to further the cause of enhancing affordability and access to medicines in line with its commitment to lower the cost of quality medical products.

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H.E. Ms. Nardi Suño Iturry, Ambassador and Permanent Representative of Bolivia in Geneva outlined Bolivia's work in recognition of its rich traditional knowledge, cultural expressions and traditional medicines. She acknowledged President Morales' focus on human rights that led to the implementation of these policies. For example, the practice of ancestral medical techniques by the Kallawayas ethnic group has been inscribed on the UNESCO Representative List of the Intangible Cultural Heritage of Humanity. Bolivia is rich in medicinal plants (for instance the coca leaf) that are useful to treat a series of discomforts and serve as a base for traditional medicine.

The Ministry of Health of Bolivia has a Vice Ministry of Traditional Medicine.

Traditional medicine is encouraged through Bolivia's Constitution, making the state responsible to promote and guarantee the respect, use and research of it, and its practice. Bolivia has adopted a new model called Intercultural Community Family Health based on community participation, intersectorality, interculturality and integrality. A "Law of Traditional Medicine and Bolivian Ancestry" was adopted to promote education and research in this domain. The Ministry of Health of Bolivia has a Vice Ministry of Traditional Medicine and Interculturality to promote this. Pharmacopoeia is also promoted for the development of medical or semi-industrial medical products based on traditional medicine. A series of instruments and institutional mechanisms promote the articulation and complementation between conventional medicine and traditional medicine.

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Bolivia is severely affected by diseases such as Chagas, Dengue, Zika, Chikungunya, Malaria, and haemorrhagic fever. Bolivia is promoting a Pharmaceutical Industrial Center for price control and a dedicated area for traditional medicines. Noncommunicable diseases are responsible for 80% of the mortality in Bolivia. Cancer is one of the country's top public health concerns with treatment being inaccessible to the average population. Bolivia has approved "Regulations for the suppliers,

prices and purchase of essential drugs and medical devices” in the market due to national shortfall in production and high costs internationally. Bolivia has adopted the “Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property”.

The Ambassador made the audience aware of the pressure witnessed by some powerful governments on other vulnerable countries not to use TRIPS flexibilities for trade reasons. She confirmed with regret instances of this happened more than once in the Latin American region.

She concluded with supporting the need to promote necessary institutional mechanisms and recommendations of UNHLP. She also shared the concerns of lack of transparency in international trade negotiations. Health and access to medicines require a human rights and public health approach, and we should work together for it.

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Taking advantage of WTO's temporary waiver, Uganda has begun developing its own pharmaceutical industry.

H.E. Dr. Jane Ruth Aceng, Minister of Health, Republic of Uganda drew upon the lessons learnt by one of the least developed countries and beneficiaries of the WTO waiver from the TRIPS flexibilities until 2033. Uganda ratified the WTO decision to make this waiver permanent in 2010.

The Minister made participants aware of the high disease burden, including the frequent public health outbreaks and lack of adequate capacity to produce all medicines required, and hence having to rely on other countries' producers, especially on India under the "compulsory licensing" arrangements.

The Minister said, firstly, taking advantage of WTO's temporary waiver, Uganda has begun developing its own pharmaceutical industry. The Minister highlighted the joint venture between a large Indian generic manufacturer and local investors to produce antiretroviral

therapy (ART) and artemisinin-based combination therapy (ACT). She explained that the government signed an off-take agreement with the company to support this undertaking. Since they have started to capture the regional market, she committed to procure the required ACT for treatment of malaria, and antiretroviral drugs (ARVs) for HIV and AIDS, as long as prices are competitive internationally.

Secondly, the Uganda National Enterprise Corporation (NEC), a state-owned corporation, is aiming to attract manufacturers of quality branded generics from developing countries to establish manufacturing plants.

Thirdly, local investors are collaborating with a Dubai-based company to start manufacturing quality medicines with technology transfer from reputable manufacturing sites.

Finally, the Minister concluded by saying that Uganda is working hard to take advantage of the temporary waiver to ensure that by the time the waiver is lifted, sufficient technology will have been transferred for Uganda to be competitive, and continue to avail of affordable medicines for the country and the region.

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H.E. Mr. Edgar Rivera, Vice Minister, Ministry People's Power for Health, Venezuela recalled that access to medicines is a great challenge that affects the full right to health and other sustainable development objectives. To date, millions of people do not have access to high quality and affordable treatments.

He was clear and emphatic in stating that barriers in accessing medicines are an ideological, conceptual and political problem that has evidenced the contradictions between the right and access to health, and has seen health as a commodity. He acknowledged that Venezuela is not outside these contradictions and has deployed a significant number of actions to ensure fairness, the rational use of

safe, effective, quality medicines with a humanistic approach that places citizens at the centre of all policy.

He expressed the intention of Venezuela to establish a permanent and binding body of all government institutions and private actors from the pharmaceutical sector. This would assist in stimulating adequate distribution, rational use of medicines and final dispensation, thereby ensuring timely access to fair prices, stimulating national production of medicines and importation of the necessary medicine products. Venezuela's government has called this policy a Pharmaceutical Engine. Venezuela also intends to create a platform for citizens to be informed of the availability of medicines. The Vice Minister explained that price control policies could be counterproductive in their impacts.

Globally, the international pharmaceutical companies place states in weak positions and intellectual property rights in opposition to health rights. There is need to refocus on population and human use and not be limited by the pharma industry.

He said that the population should be empowered by stakeholders. He concluded by informing attendees that Venezuela was also cooperating with Cuba and India on technology transfer and production of medicines.

Globally, the international pharmaceutical companies place states in weak positions and intellectual property rights in opposition to health rights. There is need to refocus on population and human use and not be limited by the pharma industry.



Ms. Maria-Luisa Silva, Director of UNDP Geneva reiterated the simple message: No one should suffer because she or he cannot afford health technologies. UNDP – Secretariat to the High-Level Panel – recalled that access affects people everywhere, not only in the “poor countries”. Ms. Silva explained that pace of innovation does not correspond to growth in the need to help patients suffering from illnesses such as malaria, tuberculosis, or neglected tropical diseases. Instances where investments have been made for a safe and effective medicine or technology are often prohibitively expensive and unaffordable to individual patients and health systems in low, middle and high-income countries alike.

No one should suffer because she or he cannot afford health technologies.

She welcomed the UNHLP report as a practical action plan to accelerate the goals of the 2030 agenda. She quoted the Netherlands recently speaking in support of the UNHLP recommendations in *The Lancet*: “We need meaningful efforts by both the pharmaceutical industry and governments to invest in new

medicines, provide full transparency on costs, prices; who pays what beforehand, and respect the legal space for governments to protect public health.”

She concluded highlighting the support given by UNDP to 18 countries to adapt and use their medicines, competition and patent laws, policies and procurement practices to increase access to more affordable treatment. She said much more can and must be done, and the international organizations, civil society, governments and private sector partners, all must act decisively to improve health technology innovation and access.

We need meaningful efforts by both the pharmaceutical industry and governments to invest in new medicines, provide full transparency on costs, prices; who pays what beforehand, and respect the legal space for governments to protect public health.



Mr. German Velasquez, Special Adviser for Health, South Centre expressed support for the expansion of the attitude to implement the UNHLP recommendations and to incorporate them into national health and medicine policies. He mentioned a recent seminar wherein the Minister of Health of Columbia asked governmental and non-governmental organizations, and industry on how they were planning to implement the UNHLP recommendations. He noted that South Centre is available to collaborate with countries in implementing the recommendations. Countries to consider

setting up inter-country process for this and the possibility to negotiate a treaty on how to finance research on pharmaceutical products.

He informed attendees about the WHA Agenda Item 70/20 that will address the global shortage of medicines, discuss the UNHLP report on access to medicines, and encouraged WHO to continue to take leadership on such issues. He called upon countries to consider taking a decision on setting up an inter-country process on the implementation of the UNHLP recommendations, and the possibility to negotiate a treaty on how to finance research on pharmaceutical products.

Mr. Velasquez highlighted the WHO Director General's availability to support the agenda on access to medicines.

South Centre is available to collaborate with countries in the implementation of the recommendations. Countries could consider setting up an inter-country process for this and the possibility to negotiate a treaty on how to finance research on pharmaceutical products.





Dr Joe Thomas, Executive Director, Partners in Population and Development highlighted three of the side event’s sponsors – Morocco, India and Uganda – as PPD member countries, and acknowledged the tireless efforts of India and other countries to lobby with the WHO Executive Board to introduce the issue of access to medicines in the WHA agenda.

He stressed that South-South Cooperation and direct collaboration between PPD member countries have resulted in considerable improvements regarding access to medicines for family planning and women’s health. Dr. Thomas underlined that PPD is at the disposal of countries to further deepen and mobilize South-South Cooperation and exchange in the implementation of the UNHLP recommendations through sharing of knowledge, capacity building, commodity and technology transfer,

assisting in shaping regulatory mechanisms and policy and advocacy dialogue between the countries.

He regretted that South-South Cooperation was often forgotten by international organizations and expressed hope that this was going to change at WHO, especially with its new Director-General hailing from a member country of PPD from the Global South. He concluded by calling upon the WHO Director-General to take necessary action in implementing the proposed Joint Declaration and announced that PPD and its member countries will engage in this process with great interest.

South-South Cooperation and direct collaboration between PPD member countries have resulted in considerable improvements regarding access to medicines for family planning and women’s health. PPD is at the disposal of countries to further deepen and mobilize South-South Cooperation on knowledge sharing, capacity building, commodity and technology transfer, assisting in shaping regulatory mechanisms and policy and advocacy dialogue between the countries.



Summary of Interactive Discussion

The Vice-Minister of Health of Ecuador declared that Ecuador aligned with the UNHLP recommendations. He illustrated that Ecuador has improved its market framework, thereby giving access to 81 medicines. He encouraged governments to work with all relevant sectors and called for international cooperation for better research and development, and to identify regional capacity to produce jointly.

Responding to a question on the access to morphine, **Ms. Dreifuss** explained that access to morphine was not addressed by the UNHLP, as it was no longer subject to intellectual property rights. She drew attention to the report of the Global Commission on Drug Policy, thereby confirming that the expiration of patents has actually reduced access to essential pharmaceuticals, pain alleviation and palliative care.

Ms. Dreifuss stressed WHO's role in the negotiations on the implementation of the UNHLP recommendations, and recalled the importance of regional mutual support in the context of WTO issues, national scope and regional solidarity.

A question on South-South technology transfers was answered by the **Moroccan representative** who informed attendees of his country's openness toward other African countries in the context of South-South Cooperation, with several ongoing projects. **Uganda** reiterated the incentives the country is offering to attract foreign investments and capital, including from South countries and manufacturers.

Dr. Marie-Paul Kieny, Assistant Director General, WHO informed attendees that the WHA agenda was rewritten to include both shortage of and access to medicines. She informed that WHO is developing a database containing the cost of production of items on the WHO essential medicines list to serve as a benchmark for prices. Dr Kieny anticipated further improvement of this database together with experts and Member States, to achieve the goal of UHC.

Conclusion and Adoption of the Joint Declaration

The Moderator of the side event, **Dr. Denis Broun, Member of the UNHLP Expert Advisory Group; Permanent Observer of PPD to the United Nations Office and other International Organizations in Geneva** summarized the rich exchange on issues that countries face in mobilizing complimentary policies to improve access to medicines.

He reiterated the importance of the UNHLP recommendations to address issues of incoherence between intellectual property rules, trade rules and public health. He acknowledged that the recommendations received an overwhelming support and countries are willing to implement them in their respective national policies.

The participants were encouraged to support and endorse the Joint Declaration adopted by the sponsors and the co-sponsors of the side event, at <http://partners-popdev.org/wha-may2017/>

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Plurinational State of Bolivia

Co-Sponsored by:



Republic of Uganda



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Republic of India



Bolivarian Republic of Venezuela

Joint Declaration of the Side Event of the Seventieth World Health Assembly

on

Impact of the Recommendations of United Nations Secretary-General's High-Level Panel on Access to Medicines in the Context of the 2030 Agenda for Sustainable Development

24 May 2017

Considering the importance of work and report of the High-Level Panel on Access to Medicines convened by the United Nations Secretary-General in light of the 2030 Agenda for Development and the Sustainable Development Goals;

Recalling that the Constitution of the World Health Organization shall be the enjoyment of the highest attainable standard of health as one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition;

Taking into account that the attainment of the highest standards of health requires focused interventions; and its pre-eminent function is to act as the directing and coordinating authority on international health work;

Acknowledging the four main objectives of WHO's medicines strategy, namely to frame and implement policy; ensure access; ensure quality, safety and efficacy; and promote rational use of medicines;

Noting further the role of WHO to provide full support and technical cooperation to Member States.

We, the Sponsors and Co-Sponsors of the Side Event at the World Health Assembly 2017,

Call upon WHO Member States to strengthen co-operation and share initiatives and lessons learned on access to medicines;

Reiterate the recommendation of the High-Level Panel to convene a United Nations General Assembly Special Session no later than 2018, to agree on strategies and an accountability framework that will accelerate efforts towards promoting health technology innovation and ensuring access;

Request the WHO Director-General to facilitate implementation of this Joint Declaration.

Please support this Joint Declaration at <http://partners-popdev.org/wha-may2017/>

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UN SG's High-Level Panel On Access To Medicines



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