



Human Rights Council
SOCIAL FORUM
18 – 20 February 2015
Room XII, Palais des Nations, Geneva

Programme of Work with Speakers' Presentation Topics and Abstracts

Theme:

“Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, including best practices in this regard.”

Wednesday 18 February 2015

10h00-10h30 Opening of the Social Forum

H.E. Mr. Faisal Bin Abdullah Al-Henzab, Chairperson-Rapporteur of the Social Forum

Ms. Jane Connors, Director, Research and Right to Development Division, OHCHR

H. E. Mr. Joachim Rücker, President of the Human Rights Council

10h30-11h15 Keynote speakers

Dr. Deqo Mohamed, Chief Executive Officer, Dr. Hawa Abdi Foundation

Dr. Jorge Bermudez, Vice-President of Health Production and Innovation, Fundação Oswaldo Cruz, Ministry of Health (Brazil)

Access to medicines: What about affordability?

Thirty years have elapsed since the Nairobi Conference on the rational use of medicines as a necessary component of ensuring access to medicines. Global, regional and national action was already foreseen as necessary to ensure safe prescription of medicines and a reliable supply chain throughout health systems.

Controversies have also arisen around health and trade and the impact of trade on access to medicines. In that context, the WTO TRIPS Agreement and free trade agreements being implemented around the world have made this issue one of high priority in the World Health Organization, in spite of the reluctance to address trade and intellectual property matters because of the polemics involved.

Brazil has been vocal in confronting the issues of health and trade placing the interaction between promoting innovation and increasing access to critical health products high on the health agenda. Brazil's constitution guarantees access to health as a State duty and a right for all. It has enshrined different public policies aimed at ensuring universal access and a free-of-charge system, even taking into account that Brazil has a population now estimated at more than 200 million.

The Doha Declaration, the Commission on Intellectual Property Rights, Innovation and Public Health, and the attempt to discuss and reach a balance between innovation and

public health are being undermined by the pharmaceutical industry launching new, innovative, effective, yet unaffordable products as exemplified by recent treatments for hepatitis C and oncologic medicines.

This presentation will discuss how to develop policies that can overcome the intellectual property barriers that build monopolies, oligopolies and cartels and hamper access to life-saving medicines.

Mr. Stephen Lewis, Co-Founder and Co-Director, AIDS-Free World, Former UN Secretary-General's Special Envoy for HIV/AIDS in Africa

11h15-11h45 General statements by participants

11h45-12h30 Overview of access to medicines in the context of the right to health

Moderator: Ms. Lynn Gentile Human Rights and Economic and Social Issues Section, OHCHR

Dr. Zafar Mirza, Coordinator, Public Health, Innovation, Intellectual Property and Trade, WHO

Overview of access to medicines in the context of the right to health: WHO Perspective and Contribution

Equitable access to medicines is an essential component of health care systems without which universal health coverage is not possible. It is recognized as an integral component of the human right to health. However, access to medicines is a complex issue which is dependent on a host of global and local variables and is defined and approached in various ways. This presentation will first introduce and position access to medicines in the context of health systems. It will then address its relevance and importance as a component of the human right to health. In this connection WHO work will also be introduced.

With a view to set the scene, the debate on access to medicines will be organized according to five sets of issues. The presentation will address 1) definitional and conceptual issues in access to medicines; 2) quality of medicines and the role of regulatory authorities; 3) access to existing medicines, both generic and patent protected 4) R&D and innovation for new essential medicines for diseases that disproportionately affect people in developing countries and how to overcome market failures in this area; and 5) access to medicines , for

vulnerable populations i.e. those in need of humanitarian assistance during emergencies, children, women and older persons; and access to controlled medicines. WHO work to address these issues and major initiatives to improve access to medicines will be presented throughout.

Mr. Martin Khor, Executive Director, South Centre

Addressing the challenge of access to medicines in the context of the Right to Health

Affordable and effective access to medicines, especially for the poor, is a key component of the Right to Health. This is a key issue, indeed a key demand, of people in developing countries. There are a range of barriers to access to medicines which together constitute national and international obstacles to the realisation of the right to health and the right to development. It is imperative to address these obstacles so as to realise the full enjoyment of the right to health. This presentation will address measures to access medicines at affordable prices, what is needed for the implementation of universal health coverage, and access to medicines in relation to emerging diseases such as Ebola and the fight against antibiotic resistance, which is one of the greatest challenges to global public health.

Dr. Dainius Pūras, United Nations Special Rapporteur on the Right to Health

Framing a rights-based approach to access to medicines

The provision of medicines to all persons based on the principle of non-discrimination is a core component of the right to the enjoyment of the highest attainable standard of physical and mental health. Medical care in the event of sickness, as well as the prevention, treatment and control of diseases depend on timely access to quality medicines.

States not only have an obligation to ensure the quality, safety and efficacy of medicines through regulatory mechanisms, but they should also facilitate the availability, accessibility, and affordability of those medicines.

While States have the primary responsibility for realising the right to the highest attainable standard of health, satisfactory health outcomes may often depend on cooperation with international organisations, including non-governmental organisations and the private sector, to improve conditions at the national, regional and international levels.

Access to medicines must be considered through a human rights framework, and must be grounded on the principles of equity, non-discrimination, participation, access to information, and accountability. Providing affordable medicines requires not only political good-will, but an efficient and functional domestic health system, and an equitable international framework.

For instance, regarding access to medicines in the context of mental health care, psychotropic medicines are an important part of the list of essential medicines, but they need to be administered in conjunction with psychosocial interventions and within a human rights framework. In mental health, as in other healthcare areas, unethical practices of overuse and misuse of medicines should be prevented.

12h30-13h00 **Interactive Dialogue**

13h00-15h00 **LUNCH BREAK**

15h00-15h45 **Improving health delivery systems in challenging contexts**

Moderator: Mr. Willem van de Put, Director, HealthNet TPO

Dr. Abdul Majeed Siddiqi, Head of Mission, HealthNet TPO Afghanistan

Fragile states and fragile access; to the right care and medication for mentally ill patients

Mental health distress and psychological suffering amidst ongoing violence and insecurity has been on the international agenda since the early 90s. 'Bridging the mental health treatment gap' is an ongoing process aimed at improving access to mental health care and services in low-income countries and fragile states. HealthNet TPO is involved in this process at the national and global level. HealthNet TPO aims to contribute to global initiatives while focusing on strengthening health systems in the areas we work including by promoting mental healthcare at all levels and within communities.

Over the years, HealthNet TPO has tackled challenges in creating reliable, effective and sustainable mental healthcare services in innovative ways. This presentation will highlight elements of this work that deal with different populations and require looking at health systems as a whole. Understanding cultural differences and identifying interventions that work for prevention of mental health problems at the grassroots level of individual households and communities is also critical to this work and allows HealthNet TPO to devise strategies to provide treatment for the most common disorders within primary health care systems and to address the challenges of improving health systems including through increased access to skilled staff and medication.

Mr. Mahmoud Daher, Head of Gaza Sub-Office-oPt, WHO

Occupied Palestinian Territory and Access to Medicines

The right to health includes access to medicines. Shortages in essential medicines indicate problems in a health system's ability to manage resources in relation to needs of the population. In the occupied Palestinian territory, the structural constraints of military occupation have impeded Palestinian development since 1967, weakening the overall socio-economic and political environment of the 4.2 million Palestinians living there and negatively affecting the functioning of the Palestinian health system. Severe movement restrictions on people and goods caused by the Israeli blockade of Gaza and Egypt's closure of the Rafah border, as well as lower health expenditures from the Palestinian Authority as a result of reduced donor aid and internal political conflict have created a fragile public health system.

Multiple external and internal factors have given rise to chronic shortages in essential medicines averaging 30% over the past 5 years, and up to 50% in medical disposables. Fuel supplies, equipment needs and ability to meet salary payments are also in question, especially in Gaza. The health system was unprepared for the humanitarian crisis witnessed during the summer 2014 attacks on Gaza, when it was overwhelmed with 10,000 injured persons and damage to one half of all hospitals and clinics. The Palestinian health sector will continue to struggle to meet patients' needs until the structural reasons for shortages are addressed and barriers to free access, control over resources and planning, economic and educational opportunities, and self-determination are removed.

Msgr. Robert J. Vitillo, Head of *Caritas Internationalis* Delegation to the UN in Geneva

"Frustrations" and "Progress" with efforts to strengthen health care systems in challenging contexts.

In emergencies, challenges come from a broad range of complex social, political, environmental, economic, military and health factors, among others. This presentation will consider two examples, one from coastal West Africa in the midst of the recent Ebola outbreak, and another from the Nuba Mountains in the midst of conflict between the government of the majority population and the resistance of a minority population. Root causes and experiences of progress and /or frustration will be examined from a human rights perspective.

15h45-16h30 **Interactive Dialogue**

Moderator: Ms. Jyoti Sangera, Chief, Human Rights and Economic and Social Issues Section, OHCHR

Dr. Raffaella Schiavon, General Director, Ipas Mexico

Access to essential maternal and reproductive drugs: where are we?

This presentation will discuss a review of Maternal and Reproductive Health Indicators at international, regional and country level. It will put special emphasis on persistent gaps in Maternal Mortality Rate (Millennium Development Goal 5a) and Contraceptive Prevalence/unmet needs, particularly among the adolescent population (Millennium Development Goal 5b) vs. the goals committed to by 2015. Mexico is presented as a case study: it shows a decline in Maternal Mortality Rate of 52.5 % in 22 years (from 89 per 100,000 Live Births in 1990 down to 42.3 in 2012) and a persistent unmet contraceptive need of one in four adolescents.

Assuring access to and guaranteeing a consistent procurement of reproductive, maternal and neonatal health -RMNH- commodities is a duty that states have in order to protect the public health and the human rights of their citizens. International agencies and organizations (WHO, Reproductive Health Supplies Coalition, the Partnership for Maternal, Newborn & Child Health) have integrated Model Lists of Essential Medicines (EMs) and interventions, that may significantly impact women's and children's lives and health.

This presentation will look at recent world and regional data describing access to two specific classes of EMs included in this list: the emergency contraceptive pill, and a synthetic prostaglandin with oxytocic action (misoprostol), for prophylaxis and treatment of obstetrical haemorrhage, including incomplete abortion. Again, Mexico will serve as a case study, to illustrate how evidence-based recommendations and civil society efforts have helped overcome ideological and technical barriers to increase access to these essential and life-saving medicines.

Dr. Tarek Meguid, Associate Professor, State University of Zanzibar

Access to Medicines for Women and Children: Causes and Associations

Dr. Lingli Zhang, Professor and Director of Pharmacy, West China Second University Hospital, Sichuan University

Reception hosted by the Permanent Mission to Qatar

Thursday 19 February 2015

10h00-10h45 Intellectual property rights and access to medicines

Moderator: Mr. Nirmalya Syam, Programme Officer, Innovation and Access to Knowledge, South Centre

Ms. Lisa Forman, Assistant Professor, Dalla Lana School of Public Health, University of Toronto .

Access to medicines, intellectual property rights and human rights

This presentation will explore the evolution of trade-related intellectual property rights and their impact on access to medicines in low and middle-income countries, locating same within the landscape of human rights and global governance. The global HIV/AIDS pandemic illustrated the human rights impacts of restrictive pharmaceutical patents in stark terms. In response, human rights actors and institutions advanced rights to health, life and development in relation to medicines, intellectual property rights and global trade practices. These efforts provoked important institutional responses at the global level, from new funding mechanisms like the Global Fund, to the Global Strategy on Public Health, Innovation and Intellectual Property and the inclusion of medicines access within the Millennium Development Goals and their potential successors. Despite these thick layers of institutional activity, there have been limited material gains in access on the ground, and the expansive growth of increasingly stringent intellectual property rights has continued relatively uninterrupted. This presentation will survey this landscape and consider possible pathways forward.

Ms. Thamara Romero, Legal Officer, Intellectual Property Unit, Division on Investment and Enterprise, UNCTAD

UNCTAD's Work in the Area of Intellectual Property Rights and Access to Medicines

Responding to the mandate received from Member States at the Ministerial Conference in Doha as well as to intergovernmental requests under the WIPO Development Agenda and the World Health Assembly's Resolution 61.21, the UNCTAD Secretariat through its Intellectual Property (IP) Unit, implements a work programme on the development dimensions of IP rights. The IP Unit assists developing countries and least-developed countries (LDCs) in particular, to establish domestic intellectual property regimes that facilitate increased access to affordable medicines; and where feasible, create local or regional pharmaceutical production and supply capacities.

Research studies conducted by UNCTAD and WHO concluded that local production may promote access to medicines. There is an increased need to diversify the supply of medicines in order to guarantee health security. However, coherence among policies in areas such as health, industrial development and IP are needed to make local pharmaceutical production an effective tool for improved access to medicines. The implementation of undefined TRIPS language provides an opportunity for governments to tailor their laws and policies to strike a desired balance between the exclusive rights promoted by IP and right to health.

Mr. Antony Taubman, Director, Intellectual Property Division (TRIPS, Government Procurement Agreement, Competition Policy), WTO

Ms. Petina Gappah, Counsel, Advisory Centre on WTO Law

The Paragraph 6 System in the WTO: Reflections on the use of compulsory licenses for public health

In November 2001, WTO made a significant decision on TRIPS and public health. In a declaration adopted in Doha by the Ministerial Conference, the WTO's highest decision-making body, the WTO recognised "the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics".

In the three years following this statement, the WTO undertook a process to clarify and amend the TRIPS Agreement to allow developing countries to respond better to public health emergencies in their territories. The most significant amendment was the approval of a process called the "Paragraph 6 system". Under this system, the WTO allows countries with insufficient or no manufacturing capacities in the pharmaceutical sector to issue compulsory licenses to import generic drugs from those countries that have the manufacturing capacity. The countries with manufacturing capacity also have to issue compulsory licences to allow the requested products to be exported from their territories.

This system, has, however, only been used once since it was adopted. In 2007, Rwanda issued a compulsory licence to import drugs from Canada, which issued a parallel licence to export the drugs requested by Rwanda. My presentation will highlight the amendments to the TRIPS Agreement that have been agreed at the WTO, the legal steps that Canada and Rwanda had to take under the Paragraph 6 system and conclude with general reflections on the use of compulsory licences by developing countries.

11h30-12h15 **Lessons learned from and emerging challenges in the global response to AIDS**

Moderator: Dr Mariangela Simão, Director of the Department on Rights, Gender, Prevention and Community Mobilization, UNAIDS

Mr. Martin Choo, Asia Pacific Network of People Living with HIV/AIDS (APN+)

Equitable Access + Effective Treatment: Community-Centered Social Movement in the Asia Pacific for Positive Change

Combination antiretroviral therapy (cART) has changed HIV from a death sentence to a manageable chronic disease. People living with HIV (PLHIV) on cART can now expect a near normal lifespan if they initiate treatment early and remain consistently adherent to treatment throughout their lives. Recent research has also found that PLHIV on effective HIV treatment and who have undetectable viral loads can prevent viral transmission during vaginal and anal intercourse. This means that HIV treatment not only benefits the individual but is also a public good. However, not everyone has equitable access to HIV treatment, or is able to achieve optimum treatment efficacy. This presentation describes the social movement of the Asia Pacific Network of People Living with HIV for equitable treatment access and effective treatment by and for its members. The presentation draws on a peer-led study completed in 2014 with 360 community members living longer (10 or more years) with HIV in the Asia Pacific, and highlights the importance of including mental health in the compendium of HIV treatment and care packages.

Ms. Alma de León, Regional Director, International Treatment Preparedness Coalition (Latin America and the Caribbean)

Activism, Good Practices, Challenges and Recommendations

Activism: I will introduce my experiences related to more than 10 years of working on the promotion and defense of Human Rights in the context of HIV and addressing the social determinants and structural problems that countries have faced and continue to face in treating patients. My career which began in Guatemala with an alliance of organizations seeking comprehensive care for people with HIV now spans the regional level.

Since 2008, the International Treatment Preparedness Coalition ITPC has focused on access to treatment for all who need it including through its Build / Community Mobilization, Advocate, Know campaign to promote access to treatment.

Build / Community Mobilization: This has involved mobilizing small grants from the Collaborative Fund for HIV to empower people. Around 100 organizations at the regional level have benefitted from this work which includes a new program entitled Bridging the Gaps BtG in which we have focused on improving understanding of HIV treatment, and incidence in populations at higher risk.

Advocate: We have developed community observatories that exercise citizen oversight to improve the response to HIV in 6 countries in the Latin American region by monitoring the provision of services from the health system, foreseeing possible shortages of antiretroviral drugs and taking necessary preventative action.

Know: We have developed several studies on human rights, treatment, and intellectual property, including a comparative study of drug prices of ARVs and related factors in Ecuador, Honduras, Guatemala, Nicaragua and Peru that looked at the impacts of IP laws on drug prices across regions and countries.

While we have made great organizational progress, improved the academic training of people with HIV, and provided support for people living with HIV through home visits that demonstrably improve adherence and thereby also contribute to reducing the risk of new infection, much work remains to be done.

We must continue to educate and strengthen the leadership of various populations and people with HIV, expand their political participation and mobilize communities in the design and delivery of health services. To promote better outcomes we must overcome obstacles that disrupt supplies of essential medicines. This will require citizen action, multi-stakeholder organization, State compliance with local and international agreements, strengthened health systems, and better decisions about the patentability and protection of data on life-saving antiretroviral drugs.

Mr. Tenu Avafia, Policy Adviser, HIV, Health and Development Practice, Bureau for Development Policy, UNDP

The Global Commission on HIV and the law: Translating its findings into practice

The unprecedented scale up of antiretroviral treatment in the past decade would not have been possible without the drastic price reductions from over US\$ 10 000 to a little more than US\$ 100 per patient per year for first line WHO approved antiretroviral therapy. This decline is largely attributed to competition from generic manufacturers and the availability of multilateral funding mechanisms. Yet, significant challenges remain. Evolving treatment needs require the use of newer, more expensive medicines, many of which remain under patent. Moreover, middle income countries are increasingly being left out of special licensing and pricing arrangements available to low income countries.

Increasingly, calls are being made for fresh approaches to address the twin challenges of innovation and access including by the Global Commission on HIV and the Law. The Commission, convened by UNDP on behalf of the UN joint programme on HIV/AIDS in 2010 interrogated the relationship between legal responses, human rights and HIV. In its 2012 report, the Commission called for countries to make full use of policy space available in domestic legislation and to proactively use other areas such as competition and procurement laws to increase access to treatment. This presentation unpacks the findings and recommendations of the Global Commission and examines ways that counties can address the twin challenges of innovation and access.

12h15-13h00 Interactive Dialogue

13h00-15h00 LUNCH BREAK

15h00-15h45 Patient-centred approaches to access to medicines

Moderator: Ms. Dragana Korljan, Coordinator, Justice, Protection and Social Rights Unit, OHCHR

Ms. Regina M.N. Kamoga, Executive Director, Community Health and Information Network Uganda

Promoting a patient-centred approach to access to medicines

Patient-centred care is health care that is responsive to the individual patients' preferences, needs and values, ensuring that patient needs guide clinical decisions. Access to medicines is one of the key elements of health and achievement of the right to health guaranteed by international law.

New ways to access medicines must consider patient circumstances and health system limitations in low and middle income (LMIC) countries.

Patient-centred interventions should address medicine access challenges in operational or consumer level medicine access models. Some of the following techniques can be used:

1. **Outreach initiatives:** Providers and [potential] clients meet at a central, more convenient location and care services including medical commodities are made accessible to beneficiaries

2. **Peer care service:** “Experienced” patients are tasked with enrolling and supporting non-experienced patients within their locality to access and properly utilize medicines.
3. **Treatment groups:** In areas of low access due to distances, groups of patients fundraise for one colleague to go to the refill facility and pick up medicines for all clients within their group.
4. **Integrated health care services:** Some pharmaceutical products i.e. vaccine programs have less funding mechanisms to attract innovative scaling up approaches. However, there are programs that support medical access initiatives.
5. **Advocacy initiatives:** Village health teams and community workers can promote priority access through community safe medicine and patient advocacy.

Sustainability of these novel approaches is still a challenge. Most of the approaches rely heavily on voluntarism and are disease specific. Efforts to seek long-term improved health outcomes need to focus on health systems strengthening.

Mr. Dmitry Borisov, Executive Director, Equal Right to Life (Russia)

Taking a patient-oriented approach to health care reforms.

Despite the legal rights of Russian citizens to full and adequate access to medical aid, many patients in Russia die because of inadequate care caused by problems in the health care financial system. Budget planning and financial management in Russian health care are still primarily oriented towards financial indicators and don't consider clinical results of treatment as the main efficacy indicator. Disease incidence and mortality control systems that are currently being used in Russia have mostly become outdated; thus, available health statistics are inadequate for proper planning. Moreover, these systems never undergo external independent audit and relevant information is therefore excluded when planning the budget.

As a result, the system of financial provision of health care functions within a fixed budget volume that doesn't correlate with existing demands for medical aid. In the current situation it is extremely important for the State to acknowledge that existing resources for health care do not ensure social commitments and State guarantees made in relevant legislation. To raise the level of transparency of the system of assurance of citizens' right to medical aid, it is necessary to implement unified clinical standards, which will be 100% financially covered by the State and partially by the population mainly via the system of co-financing (voluntary insurance). Development of this approach may in the short-term perspective influence non-infectious disease mortality rate, which still remains high in Russia. Equal Right to Life advocates for necessary changes to promote access to medicines for all.

Dr. Noel Hayman, Clinical Director, Inala Indigenous Health Service (Brisbane, Australia)

Striving towards a Centre of Excellence in Indigenous Primary Health Care: The Inala experience.

Lack of appropriate health service provision for Aboriginal and Torres Strait people is an important social determinant of their health. Historically, health services have been absent or inappropriate. Cultural factors, financial factors and distance from health services have been important barriers limiting indigenous access to mainstream health services.

The Inala Indigenous Health Service (IIHS) has been able to improve Indigenous access by utilising “simple research techniques” and community engagement. From 1995 to 2015 indigenous access increased from 12 patients to over 10,000 (approximately 3,000 regular patients). IIHS conducts approximately 2,000 doctor consultations each month. Community consultation and participation were the main ingredients to improving indigenous access to health services. With improved access, the IIHS has been able to analyse 413 Adult Health Checks in 2009.

The Adult Health Checks provide an opportunity to evaluate health status, identify chronic disease risk factors and implement preventive care. High rates of cardiovascular disease risk factors were found. This information has been used to improve service delivery with access to visiting specialists. The IIHS has successfully integrated specialist care into an Indigenous primary health care setting. Cardiology, ophthalmology, endocrinology, hepatology, rehabilitation medicine and paediatrics all deliver regular clinics with much higher attendance rates compared to Hospital Outpatients Departments where attendance rates are very low.

Through the Healthy for Life program, a Commonwealth funded quality improvement program, IIHS has continued to improve health outcomes for patients over the past four years. The price of medications is a major barrier for Aboriginal and Torres Islander people filling their prescriptions. As a result of increased affordability of drugs, adherence to medications has improved dramatically at our clinic.

Health Research has also been vital to our efforts. Indigenous led research and the development of the Inala Community Jury in Aboriginal and Torres Strait Islander Health has been an empowering journey. The high quality health care provided by the IIHS has been consistently recognised by the Commonwealth Government and Queensland Health, which provided \$7M to build a Centre of Excellence in Indigenous Primary Health Care and \$2M to staff the new Centre.

Dr. Amit Sengupta, Associate Coordinator, Peoples Health Movement (India)

The Struggle to Secure the Pharmacy of the South.

While India is termed as the 'Pharmacy of the South' as a supplier of low cost generic medicines to many Low and Middle Income Countries (LMICs), the highest numbers of people in the world (about 70% of the Indian population) who do not have secure access to medicines live in India. The most critical factor compromising access in India relates to a very poorly developed public health system. Because of poor resourcing and outreach of the public health system, 80% of out-patient care and 60-70% of in-patient care is provided through the private sector. There has been a significant expansion of the corporate-led private sector, which influences medicines use in the country – all patients who access care through the private sector need to pay for medicines.

At the same time, the generics industry in India is of critical importance for millions of poor patients in three continents who depend on medicines from India. The changing policy landscape, both globally and within India, poses a grave threat to the continuance of India as a source of low cost generic medicines. These include the need to align Indian laws with the requirements of the TRIPS agreement, global pressures to dilute health safeguards in India's IP law, liberalisation of domestic regulations and dilution of protection to domestic industry.

Two strands of activism characterize civil society struggles to secure access to medicines. The first strand links medicines access to health system issues, including struggles to strengthen public systems. The second, more recent strand, revolves around struggles to protect health safeguards in India's IP laws against both international and domestic threats.

15h45-16h30 **Interactive Dialogue**

16h30-18h00 **Breakout discussion groups**

- Financing access to medicines and universal health coverage
- Intellectual property regimes and access to medicines
- Health systems strengthening, capacity building, community engagement and empowerment

Friday 20 February 2015

10h00-11h30 Plenary discussion

11h30-12h15 Innovative approaches to promoting access to medicines

Moderator: Mr. Jorge Bermudez, Vice-President of Health Production and Innovation, Fundação Oswaldo Cruz, Ministry of Health (Brazil)

Mr. Geoff Adlide, Director of Advocacy and Public Policy, Gavi, the Vaccine Alliance

Shaping vaccine markets to benefit the poor

Since 2011 market shaping has been explicitly articulated as a key strategic objective for Gavi, the Vaccine Alliance. Gavi's model – bringing together the skills and expertise of a variety of partners – has been successful in using significant pooled-donor funds and aggregated demand from developing countries to influence the market in favour of developing countries. Gavi's financing and business model has helped to create a more healthy market with a more secure supply of vaccines at more affordable prices.

Ms. Nana Boohene, Procurement and Supply Specialist, The Global Fund To Fight AIDS, Tuberculosis and Malaria

Mr. Rohit Malpani, Access to Medicines Campaign Director of Policy and Analysis, Médecins Sans Frontières

PUSH, PULL, POOL: Accelerating Innovation and Access to Medicines for Tuberculosis

Tuberculosis mainly affects low- and middle- income countries with 95% of cases occurring there. 1.3 million people were killed by the disease in 2012 and there were 8.6 million new cases requiring treatment. With the advent of new diagnostics like GeneXpert the confirmed numbers of multidrug-resistant (MDR) TB cases are rising and programmes are unable to cope - 16,000 patients diagnosed with MDR-TB in 2012 did not receive treatment.

MDR-TB treatment is particularly difficult, because it is long—two years of treatment including eight months of daily injections and a total of more than 14,600 pills to swallow— and because many of the medicines used have toxic side effects such as deafness, psychosis and severe nausea. Moreover, the success rate is unacceptably low with only 48% of

patients being cured, and costs can be very high. For 9% of global cases with extremely drug-resistant TB (XDR-TB) treatment is even longer, more expensive and the success rate is even lower at only 13%.

This presentation will introduce the '3P Project', which is aimed at rapidly delivering affordable, effective new regimens for TB through an open collaborative approach to conducting drug development and through novel approaches to financing and coordinating R&D. The 3P Project implements three mechanisms to facilitate necessary and appropriate R&D for TB regimens:

- push funding to finance R&D activities upfront (through grants)
- pull funding to incentivise R&D activities through the promise of financial rewards on the achievement of certain R&D objectives (through milestone prizes)
- pooling of IP to ensure open collaborative research and fair licensing for competitive production of final products.

Ms. Lena Kähler, Researcher, The Danish Institute for Human Rights

Developing Indicators on the Right to Health – the AAAQ Toolbox

The Right to the Highest Attainable Standard of Health (right to health) is like other economic, social and cultural (ESC) rights set out in the International Covenant on Economic, Social and Cultural Rights. General Comment 14 on the right to health, issued by the Committee on ESC rights, states that guaranteeing access to essential medicines as defined in the WHO model list of essential medicines is among the core obligations of State efforts to realize the right to health for everyone. As part of its research and conceptual and practical work with the Human Rights Based Approach to ESC rights, the Danish Institute for Human Rights is currently developing a Toolbox for working with ESC rights in practice.

Following a conceptualization of the right to health, access to essential medicines will be the first of four core right to health obligations undergoing analysis by means of the AAAQ toolbox. The core element in the Toolbox is an indicator framework based on the Availability, Accessibility, Acceptability and Quality (AAAQ) criteria for realisation of ESC rights. The AAAQ framework on the right to health will translate international human rights obligations including access to essential medicines into specific standards, indicators and benchmarks. It is designed as a multi-stakeholder approach and includes common methodologies and tailored tools for all stakeholders. Ultimately, the aim is to establish a clear and traceable link between rights-holders, national legislation and policies, and international human rights standards.

12h15-13h00 **Interactive Dialogue**

13h00-15h00 **LUNCH BREAK**

15h00-16h30 **Good practices in promoting access to medicines
(Roundtable)**

**Moderator: Mr. Craig Mokhiber, Chief, Development Economic and Social Issues Branch,
OHCHR**

Mr. Damiano de Felice, Strategic Adviser to the CEO, Access to Medicine Foundation

Pharmaceutical companies and access to medicine: better practices but uneven progress

The Access to Medicine Index analyses the top 20 research-based pharmaceutical companies and ranks them according to their efforts to improve access to medicines in developing countries. A total of 95 indicators make up a framework within which company performances relating to 47 high-burden diseases in 106 developing countries can be compared. The Index brings out best practices and examples, and highlights areas where critical action is required.

The 2014 Index shows that the industry has stepped up its efforts on several fronts. Policies and activities to improve access to medicines continue to get better organised. Companies are experimenting with innovative access-oriented business models, and are granting more licences to manufacturers to produce generic versions of their medicines. Since the 2012 Index, the total number of R&D partnerships has increased by 35%, mainly due to an increase in drug-discovery and early-stage partnerships targeting neglected tropical diseases, malaria and tuberculosis.

However, progress is uneven across the areas of activity that matter, with the industry struggling to perform well in two important areas. First, nearly all companies have been the subject of settlements or judgements regarding breaches in ethical marketing, bribery or corruption standards or competition laws in the last two years. Second, companies remain conservative in their disclosure of where patents are active and when they will expire – information that is very useful to medicine procurers and generics manufacturers.

Dr. Sathyanarayanan Doraiswamy, Senior Reproductive Health/ HIV Coordinator, UNHCR

Promoting access to medicines for refugees

UNHCR's health programmes are based on the concept of Primary Health Care (PHC) through which essential health services are made accessible to individuals, families and the community.

Health services are provided to refugees and other persons of concern at national health centres or through health centres supported by UNHCR and its partners. In those health services provided or supported by UNHCR and its partners, medicines, supplies and equipment necessary for preventive and curative health services are provided by UNHCR based on its Essential Medicines and Medical Supplies Policy. With this policy, UNHCR ensures that quality essential medicines and medical supplies are available, affordable, and used rationally.

Based on inter-agency and WHO guidance and within the framework of the WHO pre-qualification scheme, UNHCR uses an international procurement strategy that ensures the availability of medicines of good quality, safety and efficacy at the best value-quality price.

While in UNHCR supported health services, medicines and services are always provided free of charge to beneficiaries, national health systems may charge for services and/or medicines. UNHCR advocates for access to free primary health care, especially obstetric care and services for children under-five.

UNHCR supports the rational use of medicines through the promotion of rational clinical management and prescribing, dispensing and consumption of pharmaceuticals at all levels. To this effect, UNHCR and our partners continuously build the capacity of health workers, monitor clinical standards and provide technical support.

Ms. Soraya Ramoul, Director, Access to Health, Novo Nordisk

Novo Nordisk's Initiatives on Access to Medicines

As the largest producer of insulin in the world, we see it as our responsibility to improve access to medicines and care for the millions of people who suffer from diabetes. Diabetes is an escalating epidemic and it today affects nearly 400 million people mostly living in low and middle countries. Many need insulin to survive and to manage their conditions.

This is why Novo Nordisk made a commitment to always have low-priced insulin in our product portfolio. Novo Nordisk also took steps to improve affordability of insulin in 2001 by introducing a preferential pricing policy for least developed countries as defined by the UN.

With this policy we ensure that the insulin is offered at daily average price per patient of less than 20 cents USD. In other low and middle income countries Novo Nordisk sells insulin at equally low prices to an estimated 4 million patients through government tenders involving large volumes.

The supply chain of medicines like insulin is complex. Even if the manufacturer reduces the prices so called mark up prices make the price much higher at the pharmacy counters for patients. With the project base of the pyramid we try to build a sustainable partnership involving all actors in the distribution chain to ensure that the end price is affordable for patients.

We regard affordable prices as one component of the wider partnership required to improve healthcare capacity for prevention, diagnosis and treatment.

Mr. James Love, Director, Knowledge Ecology International

Mr. Esteban Burrone, Head of Policy, Medicines Patent Pool

Ms. Smiljka De Lussigny, Senior HIV Portfolio Manager, UNITAID

UNITAID's Good Practices in Promoting Access to Medicines

A diagram of UNITAID's role in promoting innovation in the global response to HIV, TB and malaria is available at:

<http://www.ohchr.org/Documents/Issues/SForum/SForum2015/SmiljkaDeLussigny.pdf>.

With funding for global health stagnating and decreasing in recent years, it is imperative that governments, donors and other stakeholders determine how to do more with less in order to improve access to medicines and other key health commodities needed in low-resource settings.

We still lack the tools and resources needed to diagnose and treat everyone affected by diseases like HIV – now 35 years on since the start of the epidemic – and tuberculosis, a disease affecting humans since antiquity. Most importantly, we lack technologies that are appropriate for use in populations and settings that are most in need – like better-adapted formulations of paediatric drugs for HIV, simpler, more accurate diagnostics for tuberculosis, and safer, more effective drugs for hepatitis C virus (HCV). From time to time, we see promising evolution and technological innovation in diagnosis and treatment, as is currently the case for HCV treatment. However, these life-saving innovations are too often priced out of reach for those most in need.

UNITAID is a global health initiative that intervenes to transform game-changing ideas into real-world solutions for those in need by providing funding to organizations working to demonstrate the impact, cost effectiveness, and utility of new tools and to develop the evidence needed to inform health policy and normative guidance. Through interventions focused on innovation, UNITAID helps to optimize and create demand for new products – and prove how best to use them – so that national governments and large donors like the Global Fund, PEPFAR and PMI can bring them to scale worldwide and reach more people in need.

UNITAID also helps to improve the affordability of new commodities, often by leveraging its purchasing power to negotiate with manufacturers to supply quality-assured health products at lower prices. By funding organizations like the Medicines Patent Pool, UNITAID enables generic, low-cost production of medicines by pooling relevant patents for sub-licensing and product development. UNITAID also supports work in key generic manufacturing countries like India to address patent barriers preventing generic production.

Founded in 2006 by the governments of Brazil, Chile, France, Norway and the United Kingdom, UNITAID is hosted by the World Health Organization and funds over 30 different projects in HIV, tuberculosis, malaria and HCV. UNITAID is financed by donor countries and a solidarity levy on airline tickets.

Mr. Hans Rietveld, Director, Market Access and Capacity Building, Novartis Malaria Initiative, Novartis Pharma AG

Novartis Malaria Initiative - Innovating to help eliminate malaria

One of our key corporate responsibility ambitions is to expand access to healthcare. We focus our work in three areas, where we believe we can make the most impact:

1. Contribute to efforts to control and eliminate diseases including leprosy and malaria
2. Advance social ventures to tackle health problems of under-served, low-income patients in both the developed and developing world
3. Focus on neglected disease research, while expanding adaptive research that targets unmet needs

Over the past decade, the Novartis Malaria Initiative has become one of the pharmaceutical industry's largest access-to-medicine programs, measured by the number of patients reached annually.

Since 2001, in collaboration with a range of public and private stakeholders, Novartis has delivered more than 700 million antimalarials without profit, including 250 million treatments of the first paediatric, sweet-tasting dispersible artemisinin-based combination (ACT) treatment, developed in collaboration with Medicines for Malaria Venture.

With *SMS for Life*, Novartis has pioneered the use of mobile technology as an enabler to expand access. The project, implemented in five African countries, provides visibility of antimalarial stock levels and prevents public health facilities from running out of treatments.

In order to enhance adherence among not yet fully literate populations, Novartis developed innovative packaging for its ACT treatment using pictograms.

Novartis is also applying its expertise in drug discovery to the next generation of antimalarials and has two new drug candidates in clinical development. Both are the first agents of new classes of antimalarials and could become the first antimalarials not belonging to the ACT class and help combat drug resistance emerging in South East Asia.

16h30-17h15	Interactive Dialogue/Closing Statements
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17h15-17h30	Summing up, Conclusions and Recommendations
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H.E. Mr. Faisal Bin Abdullah Al-Henzab, Chairperson-Rapporteur of the Social Forum

18h00	Closure of the Social Forum
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