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**Opening remarks at the joint WHO, WIPO and WTO TECHNICAL SYMPOSIUM on
INNOVATION AND ACCESS TO MEDICAL TECHNOLOGIES – CHALLENGES AND
OPPORTUNITIES FOR MIDDLE-INCOME COUNTRIES**

GENEVA, 5 November 2014, WTO CR Room

Dear Xiaozhun Yi, Dear Christian Wichard, distinguished experts, ladies and gentlemen,

Let me first convey our Director-General Margaret Chan's apologies for her absence today, due to urgent commitments to the Ebola response efforts. She very much regrets to miss this traditional coming together from the three organizations to discuss the linkages between public health, trade and intellectual property.

We are here today to discuss the specific challenges of middle-income countries with respect to innovation and access to health products.

Innovation and access have been prominent on the public health agenda for a long time. Access to essential medicines is one of the six leadership priorities of WHO. Universal health coverage, which is our guiding principle, is not possible without innovation and sustainable supply of affordable medicines and health technologies. But what are the benefits of innovation if the people who need the new medicines cannot access them?

Ladies and Gentlemen, before we can discuss access to health products, these new medicines, vaccines, and health technologies of course need to be developed and their safety, efficacy and quality assessed. The list of new products needed to improve the health of patients is long. Let me give you five examples: The world needs

1. New antibiotics and medicines to treat multi-drug resistant tuberculosis;
2. fixed-dose combinations to improve treatment compliance;
3. paediatric formulations for a range of childhood conditions;
4. medical devices and assistive health technology for aging populations, which is a demographic trend rapidly emerging in middle-income economies;
5. new and more effective vaccines.

Let us be clear, without innovation there will be none of these new products. But if there are new effective essential health products, we also have to ensure that they are affordable and accessible to those who need them - otherwise innovation remains an empty promise!

In this context, middle-income countries are facing particular challenges. The pharmaceutical industry considers many of these countries as important markets where

they want to grow. The unequal distribution of gross national income in many of these countries however means that even a high GDP does not mean that the majority of people in these countries are well off. In reality, they are home to the largest numbers of poor people globally and the absence of widespread health insurance systems means that many have to pay for medical expenditures out-of-pocket.

The increasing disease burden of non-communicable diseases puts an additional strain to the national health budgets of these countries. Our Director-General when addressing this year's World Health Assembly pointed out that according to the 2014 WHO World Cancer Report the number of new cancer cases has reached a whole time high and is projected to continue to rise, with around 70% of all cancer deaths occurring in developing countries. In some middle-income countries, diabetes treatment alone is absorbing nearly half of the entire health budget.

Unaffordable prices are not only an issue in developing countries. A recent report described the trend by showing that in the US the median revenue of the Top 100 medicines increased seven fold from \$1,260 in 2010 to \$9,400 per patient in 2014 while the patient population per specific drug is shrinking because of narrower medical indications. More and more treatments cost more than US\$100,000 per patient per year. The new hepatitis C treatments are a prominent example for this trend. Many developed countries struggle to keep health expenditures under control while providing access for those who need the new treatments. It is obvious: if not controlled, prices will continue to rise. It is also obvious that no country will be able to treat its way out of cancer, diabetes or hepatitis: Therefore we must focus even more on prevention, reducing risk factors and improve infection control.

The new treatments for hepatitis C are a good example to illustrate what WHO can contribute:

More than 185 million people are infected with the hepatitis C virus worldwide, which kills up to 500,000 people each year. HCV infection can be cured using pegylated interferon and ribavirin, but treatment duration is long, it involves weekly injections, and side effects are considerable. The new directly acting antiviral treatments are expected to reach cure rates of more than 90 % with fewer side effects and a shorter treatment duration. This is a tremendous achievement and we are thankful to those scientists who developed the medicines. These treatments can change the world of hepatitis, but only if those who need treatment can actually access it. Given that the burden of hepatitis C is concentrated in middle-income countries, achieving affordable prices for these countries is a matter of urgency.

WHO is advising a number of Member States on establishing comprehensive national hepatitis programmes covering prevention, diagnosis and how to access treatment in line with the new WHO treatment guidelines for the screening, care and treatment of persons with hepatitis C infection. To allow countries to identify their options, WHO has published

an analysis of the patent situation for seven of the new hepatitis treatments. Concurrently, the WHO prequalification programme, which assesses the quality and safety of priority medicines, vaccines, diagnostics, and active pharmaceutical ingredients, has issued the first call for expressions of interest for hepatitis C and B treatments. This is an important step to stimulate generic competition, while ensuring that generic versions of these new antivirals are compliant with quality and safety standards.

In this debate, we also have to remain objective: Unaffordable prices are by far not the only challenges for accessing medical treatment. Most of the essential medicines and treatments for heart disease, diabetes, and chronic lung diseases are available as cheap generic version and still these treatments are not available in many health facilities. Ensuring access to essential products is the primary responsibility of national governments. They must focus on building national health systems that can provide quality essential health services and products at a cost that everyone can afford.

The Ebola crisis again has showed the world that only strong health systems can prevent this kind of catastrophes. Strong health systems do not come for free. Economic growth can leverage people out of poverty and enhance living conditions, but to what extent this happens depends a lot on how the fruits of economic growth are distributed. Increase in GDP must go hand in hand with greater investment in health infrastructure, an educated and adequately remunerated health workforce and universal health coverage schemes. Governments have to make health a priority and invest accordingly in stronger health systems, of which supply of essential medicines is an important element.

Ebola has also reminded us that we have diseases where the current patent system does not deliver the innovation we need: The lack of expected return on investment was one of the major reasons why today we have to test the Canadian Ebola vaccine in a few months while this could have been done many years ago! We have been discussing this failure of the market driven R&D system for a long time. We hope that this reminder will trigger more long term financial commitments by governments, including those of middle-income countries to finance the needed research and development.

I will conclude by emphasizing that WHO will continue to play an important role at the interface of public health and intellectual property. For this however we need the expertise of other organizations: Dear Xiaozhun YI, Dear Christian Wichard, I would like to thank you and your colleagues of the WIPO and WTO Secretariat for your continued support and engagement. This trilateral cooperation is a prime example of the need for cooperation between different sectors in order to leverage opportunities and promote better, more equitable and universal access to healthcare.