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1/2

INNOVATION AND ACCESS TO MEDICAL TECHNOLOGIES

CHALLENGES AND OPPORTUNITIES FOR MIDDLE-INCOME COUNTRIES

A JOINT TECHNICAL SYMPOSIUM BY WHO, WIPO AND WTO

Geneva, 5 November, 2014, World Trade Organization

BACKGROUND NOTE¹

The Current Situation in Middle-Income Countries

Today, middle-income countries are catching up in the area of biomedical innovation and industrial development, but are also facing challenges in ensuring access to innovative health products for their populations.

Countries categorized as middle-income by the World Bank are at very different stages of economic development, ranging from a gross national income of just above US\$1,000 to more than US\$12,000 per capita.² The current 105 middle-income countries include 17 countries that, in the UN system, are considered least developed countries³, due to the different selection criteria for the two groups. While the World Bank's main criterion for classifying economies is gross national income, the United Nations Committee for Development Policy uses two additional criteria, the human asset index and the economic vulnerability index.

Given that the gross national income in many of these countries is unequally distributed, the rating as a middle-income country does not mean that the majority of people in these countries are well off. Today, more than three-quarters of poor people in the world who live on less than US\$2 per day are in middle-income countries rather than in low-income countries.

In the absence of widespread health insurance systems in many middle-income countries, patients pay most medical expenditures out-of-pocket. This means access to health services and specifically medicines in these countries remain a huge problem. If international aid and assistance focuses on

¹ This paper has been jointly drafted by the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO).

² Low income, US\$1,045 or less; lower middle income, US\$1,046 – US\$4,125; upper middle income, US\$4,126 – US\$12,745; and high income, US\$12,746 or more, <http://data.worldbank.org/about/country-and-lending-groups>.

³ Angola, Bhutan, Djibouti, Kiribati, Lao People's Democratic Republic, Lesotho, Mauritania, Samoa, Sao Tome and Principe, Senegal, Solomon Islands, the Sudan, Timor-Leste, Tuvalu, Vanuatu, Yemen, and Zambia.

low- and lower middle-income countries, there is a risk that it will increasingly miss the majority of poor people.

The innovative capacity of middle-income countries varies widely. Some countries have an increasingly sophisticated local bio-medical industry that is becoming more innovative and are attracting global companies that establish local R&D centres. In the majority however these industries are practically non-existent. Even those middle-income countries that are investing in R&D have developed few innovative biomedical products due to the huge upfront investment required and the risky nature of drug development. However, different innovation indices show that pharmaceutical companies are filing an increasing number of patents on incremental innovations, reflected in the growing number of patent applications coming out of these countries. It is also important to note that the focus of such innovation is not on neglected tropical or locally prevalent diseases, but on diseases that tend to have a global market.

Middle-income countries have often been at the heart of the debate on the impact of intellectual property (IP) on access to medicines in the past years: one of the most controversial aspects of the increasing number of voluntary license agreements in the area of antiretroviral treatment for HIV is the inclusion or exclusion of middle-income countries. With the upcoming new treatments for hepatitis C, there is even greater focus on middle-income countries that bear a very high disease burden. To achieve their public health objectives, middle-income countries appear to be adopting different IP strategies. Some of them have been at the forefront of using the so-called flexibilities contained in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to promote access to medicines and support their generic industry. Overall, different countries have adopted different strategies to achieve the longer-term aim of developing their domestic innovative industry.

Middle-income countries are also one of the most challenging markets for the pharmaceutical industry. With shrinking margins in Europe especially, companies are increasingly looking at these emerging economies as promising markets, but are struggling to find business models that are profitable on the one hand and on the other facilitate access to affordable treatment given the absence of widespread health insurance coverage. Different companies are pursuing different business models, including differential pricing, voluntary licensing and other forms of partnership with local generic companies.

The Symposium's Objectives

Against this background, the fourth technical symposium organized by the WHO, WIPO, WTO under the auspices of the ongoing trilateral cooperation, will focus on the challenges and opportunities of middle-income countries with respect to innovation and access to health products. It will shed light on the concept of rating countries according to their gross national income, in particular, why such a benchmark alone is not adequately reflecting the public health situation and what public policies are needed to ensure that economic growth contributes to achieving Universal Health Coverage. It also will examine the twin challenges of promoting biomedical innovation within middle-income countries while ensuring access to that innovation.

The symposium is the fourth in the series of joint technical symposia on public health, intellectual property and trade convened by the WHO, WIPO and the WTO. It builds on the collaborative work undertaken by the three agencies, which includes the implementation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. A major objective of this collaboration is to enhance capacity. Information about the previous symposia, as well as the joint study on Promoting Access to Medical Technologies and Innovation launched in 2013, can be accessed on the websites of the [WHO](#), [WIPO](#), and [WTO](#).
