

WTO TRIPS COUNCIL - OCTOBER 2014

AGENDA ITEM 6. REVIEW UNDER PARAGRAPH 8 OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

STATEMENT BY WHO

Honorable Chairman, distinguished delegates, ladies and gentlemen.

We seize the opportunity to present under this health-related agenda item a number of the World Health Organization's technical cooperation activities that took place since our last report to the TRIPS Council.

The overall objective of WHO's technical cooperation in the area of public health and intellectual property is to strengthen the capacity of developing countries in health innovation, access to medicines and management of intellectual property. Countries should prioritize public health interests in the formulation of national policies and legislation on trade and intellectual property.

WHO's technical cooperation is based on its mandate derived from the Global strategy and plan of action on public health, innovation and intellectual property as well as from other relevant WHO resolutions. For example, Resolution WHA67.6 on the prevention, diagnosis and treatment of viral hepatitis requested the Director-General "to assist Member States to ensure equitable access to quality, effective, affordable and safe hepatitis B and HCV treatments and diagnostics, in particular in developing countries". In 2014, contributing to the implementation of this resolution was one of the main activities in the area of public health and intellectual property.

The WHO's 2014 Guidelines for the screening, care and treatment of persons with hepatitis C infection state that more than 185 million people are infected with the hepatitis C virus worldwide. Of these people, 350 000 to 500 000 die each year. HCV infection can be cured, but most people infected with the virus are unaware of their infection and thus do not seek timely treatment. Several medicines are available to treat hepatitis C, but treatment duration is long, involves weekly injections, and side effects are considerable. With the development of new direct-acting antiviral medicines, the treatment landscape is rapidly changing. These new antivirals are expected to reach cure rates of more than 90 per cent in persons with hepatitis C virus infection across different genotypes, with fewer side effects and a shorter duration of treatment. Prices for these new treatments however are

extremely high, in particular in developed countries, but remain out of reach for many patients in developing countries as well. WHO has advised a number of Member States on how to establish national hepatitis programmes that cover all aspects reaching from prevention, to diagnosis and treatment, including on how to access the new treatments at affordable prices. Options include local production where patents have not been filed or granted, license agreements, price negotiations and compulsory licenses.

To identify their best options to increase access to and affordability of these new antiviral treatments, countries need clarity about patent status of the medicines. Therefore, in September 2014 the WHO Secretariat published an analysis of the patent situation of seven new hepatitis treatments. This corresponds to the mandate provided by the WHO Global strategy and plan of action on public health, innovation and intellectual property that requests WHO to support efforts to determine the patent status of health products. The patent working papers identify the most relevant patents with respect to the seven medicines and list the countries in which these patents have been filed and granted.

Generic competition is the single most effective means to drive prices down. In this respect the UN/WHO programme on prequalification has played a key role in ensuring the quality of mostly generic products, in particular for international procurement programmes for HIV. The prequalification programme ensures the quality and safety of all prequalified medicines, vaccines, diagnostics, and active pharmaceutical ingredients, in particular for international procurement programmes. Its mission is to make quality priority medicines available for all those in need. Given that many generic manufacturers from developing countries are not submitted to stringent regulatory control, prequalification is essential to allow for the widespread export of generic products from these manufacturers. WHO has thus decided to expand the programme to include hepatitis C and B treatments and in September 2014 has issued the first call for expressions of interest for hepatitis C and B treatments.

In the area of HIV, the new WHO Technical Report on Access to antiretroviral drugs in low and middle-income countries examines global trends in prices of antiretroviral treatment and assesses how WHO treatment guidelines have influenced the uptake of different formulations. It describes the current constraints limiting the use of second-line, third-line and pediatric treatment, and explores how the quality of antiretroviral treatment can be secured and in-country distribution can be improved. The report includes chapters on the role of intellectual property

in access to treatment, on prices, quality assurance, increasing global demand as well as on supply chain management.

Developed from the consultation on access to HIV medicines in middle-income countries held from 10 to 12 June 2013 in Brasilia, Brazil, WHO published the report Increasing access to HIV treatment in middle-income countries: Key data on prices, regulatory status, tariffs and the intellectual property situation. The paper provides information on the prices paid by 20 middle-income countries for adult and pediatric formulations of antiretroviral treatments recommended by WHO. It links pricing information with an analysis of the intellectual property situation of the selected medicines taking into account existing license agreements as well as compulsory licenses. It also includes data and general information on a number of other determinants of prices and availability of ARVs, including tariffs, mark-ups and taxes as well as the regulatory status. The data shows that middle-income countries are a heterogeneous group and that procurement prices vary widely. Middle-income countries supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria pay low prices for first-line and many second-line treatment regimens, comparable to those paid by low-income countries. Other middle-income countries pay higher prices, especially for newer second-line and third-line treatments sourced from originator producers.

More ample information on technical cooperation activities under the WHO programme on public health and intellectual property can be found in document IP/C/W/603/Add.1. We would be glad to answer any questions delegations might have regarding these activities and send you the reports mentioned by email.

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