

## INFORMAL CONSULTATION ON ACCESS TO HEPATITIS MEDICINES IN UPPER-MIDDLE-AND HIGH INCOME COUNTRIES



21–22 August 2017  
Manila, Philippines



Informal Consultation on Access to Hepatitis Medicines in Upper-Middle-and High Income Countries  
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WORLD HEALTH ORGANIZATION  
REGIONAL OFFICE FOR THE WESTERN PACIFIC

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MEETING REPORT

INFORMAL CONSULTATION ON ACCESS TO HEPATITIS MEDICINES IN  
UPPER-MIDDLE- AND HIGH-INCOME COUNTRIES

Convened by:

WORLD HEALTH ORGANIZATION  
REGIONAL OFFICE FOR THE WESTERN PACIFIC

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## NOTE

The views expressed in this report are those of the participants of the Informal Consultation on Access to Hepatitis Medicines in Upper-Middle- and High-Income Countries and do not necessarily reflect the policies of the conveners.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for Member States in the Region and for those who participated in the Informal Consultation on Access to Hepatitis Medicines in Upper-Middle- and High-Income Countries in Manila, Philippines from 21 to 22 August 2017.

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Keywords:

Hepatitis / Drugs, Essential / Health Services Accessibility
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## **SUMMARY**

The WHO Western Pacific Region has had much success in prevention of hepatitis, in particular hepatitis B through immunization. However, there is a substantial burden of people chronically infected with hepatitis B and C who have little access to treatment. In particular, new hepatitis C direct-acting antivirals (DAAs) remain expensive and are a barrier to access to treatment for all who need it.

The Informal Consultation on Access to Hepatitis Medicines in Upper-Middle- and High-Income Countries was held at the WHO Regional Office for the Western Pacific in Manila, Philippines from 21 to 22 August 2017. Presentations and discussions on regional and global approaches to dealing with intellectual property rights, financing, drug pricing, health technology assessment, and research and development of treatments for hepatitis were part of the agenda.

Participants agreed on ways forward, including consideration of joint negotiation for medicines in the Region, greater sharing of pricing information and negotiation strategies, monitoring of real world efficacy of new direct-acting antivirals, capacity-building, and platforms for information sharing.

## **1. INTRODUCTION**

### **1.1 Meeting organization**

The Informal Consultation on Access to Hepatitis Medicines in Upper-Middle- and High-Income Countries was held at the WHO Regional Office for the Western Pacific in Manila, Philippines from 21 to 22 August 2017. The meeting was organized to allow upper-middle- and high-income countries to share their experiences in increasing access to new treatments for hepatitis. Presentations and discussions on regional and global approaches to dealing with intellectual property rights, financing, drug pricing, health technology assessment, and research and development of treatments for hepatitis, were undertaken with a candid and frank exchange of ideas. The list of the participants is available in Annex 1, and the meeting agenda is outlined in Annex 2.

### **1.2 Meeting objectives**

The objectives of the meeting were:

- 1) to review approaches and barriers for improving access to hepatitis medicines in selected upper-middle- and high-income countries;
- 2) to draw lessons from pricing and access strategies undertaken by those countries; and
- 3) to discuss next steps for improving access to hepatitis medicines.

## **2. PROCEEDINGS**

### **2.1 Opening session**

Dr Shin Young-soo, WHO Regional Director for the Western Pacific, delivered the opening remarks. Dr Shin welcomed the participants and noted the regional success in the prevention of hepatitis, in particular hepatitis B. He acknowledged, however, that the treatment of hepatitis remains expensive and stated that 1200 people die each day of hepatitis in the Western Pacific Region. He encouraged participants to develop ways for the Region to meet the *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020* to reduce the morbidity and mortality due to hepatitis through increased access to effective antiviral therapy.

After the introductory address, Dr Jun-Ho Jang from the Republic of Korea and Ms Lisa Williams from New Zealand were elected as co-chairs for the meeting.

### **2.2 Session 1: Setting the scene**

Dr Ying-Ru Lo and Dr Socorro Escalante provided an overview of the current situation regarding access to treatment for hepatitis in the Western Pacific Region. They noted that the disease burden and deaths due to chronic hepatitis remains high in the Region – and is among the highest in the world. Although prevention and treatment reduces deaths from cirrhosis and cancer, they acknowledged that access to hepatitis treatment in the Western Pacific Region remains limited. Drs Lo and Escalante noted that while prices of direct-acting antivirals (DAA) for hepatitis C have been decreasing worldwide over time, the steepest decrease in price has occurred where there is generic competition, such as in Egypt and Pakistan.

Mr Andrew Rintoul outlined the global situation regarding expensive medicines and policy options for affordability and pricing. He explained that the pharmaceutical industry's goals may not always align with the desire to implement universal health coverage (UHC) and that the industry usually uses its power to be the price setter. This has resulted in the need to elevate the issue of what is a "fair price" to the global level. He acknowledged that countries need to balance industry and health policies, although engaging with the industry to build trust and certainty regarding revenue and profits is also important.

Dr Po-Lin Chan presented an overview of the current drugs to treat hepatitis. She discussed the current WHO guidelines for hepatitis and the evolving therapeutic landscape with respect to treatments, particularly for hepatitis C. Dr Chan outlined the genetic diversity as regards the genotypes affecting patients in the Western Pacific Region, and noted that the next update of the WHO guidelines would include new pan-genotypic DAA drugs, which simplify and possibly shorten the duration of treatment. Dr Chan stated that, despite these advances, multiple barriers to access still remain.

After a poster walk, during which participants were able to provide more details on the approaches to access to new hepatitis medicines in their country, there was a discussion about the barriers to increasing access to treatment. Participants identified out-of-pocket expenses through co-payments, even with better prices, as posing a significant barrier to access. In some countries, this could be as high as US\$ 2000 per year. Another barrier was the requirements for drug registration, with some countries needing local clinical trials for registration. It was reported that most countries have an expedited or priority review process for registration of some medicines. However, it was also acknowledged that registration agencies are generally reactive, waiting for pharmaceutical companies to apply for registration, and this can limit the options for treatment in the market. Access to screening for different genotypes was also identified as a potential barrier, particularly where countries do not have access to pan-genotypic treatment options. With regard to expanding access, while a number of participants expressed a desire to allow access to treatments in primary care, concerns regarding training and support for primary care physicians meant that most patients will need to access treatments through specialist clinics, at least initially until primary health treatment services are adequately prepared.

Dr Moon-Seok Choi described the current status and unmet needs for management of hepatitis in the Republic of Korea. He noted that while the number of hepatitis B patients remains steady, there is a pool of approximately 1 million people in the country who are undiagnosed, due largely to low awareness of the disease and its significance. Similar low awareness was also reported for hepatitis C infection with less than 35% of hepatitis C virus (HCV) carriers aware of their infection status. Dr

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