

## ***Key messages of the WHO 2016 update of the guidelines for treatment of persons with chronic hepatitis C infection***

*For internal briefing of WHO staff and partner agencies and not for official communication  
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### ***Why update?***

- Viral hepatitis is one of the major challenges in global health with 400 million people living with chronic infection and an estimated 1.45 million deaths every year, which exceeds the mortality of other major infectious diseases such as HIV. Among the five types of viral hepatitis, hepatitis C accounts for approximately half of the all hepatitis-related deaths (700 000 deaths/year).
- In 2015, global leaders adopted the Sustainable Development Goals for 2030 which includes specific mention of viral hepatitis. WHO is currently developing the first global strategy addressing viral hepatitis with a goal of eliminating viral hepatitis as major public health threat by 2030. It is expected to be adopted at the World Health Assembly in May this year<sup>1</sup>.
- WHO is continuing to provide comprehensive normative and policy guidance to countries in strengthening their efforts to combat hepatitis. The first-ever WHO guidelines for hepatitis treatment were released in 2014 addressing screening, care and treatment of persons with hepatitis C infection.
- Since that time, several new direct-acting antiviral medicines have been approved for the treatment of hepatitis C. Compared with older treatments, these medicines are easier to administer, shorter in duration, are better tolerated by patients, and achieve cure rates greater than 90% for most patient groups.
- WHO is now updating its hepatitis C treatment guidelines, so that countries can update their national policies and protocols for hepatitis C treatment in the hope that more patient can benefit from these improved medicines.
- On 24 February 2016, WHO is hosting a symposium on the "Early release of the new recommendations from updated guidelines for the treatment of people with chronic hepatitis C infection" at the 25<sup>th</sup> conference of the Asia Pacific Association for the Study of the Liver (APASL2016) taking place in Tokyo, Japan.<sup>2</sup> At the symposium, WHO will be sharing the key recommendations of the above mentioned guidelines with partners. WHO will also be releasing a short policy brief (attached) that summarizes the recommendations.
- The full updated WHO guidelines are planned for release at the International Liver Congress (EASL2016) taking place on 13-17 April in Barcelona, Spain<sup>3</sup>, and will be published on WHO website at that time.

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<sup>1</sup> <http://www.who.int/hepatitis/strategy2016-2021/en/>

<sup>2</sup> <http://www.apasl2016.org/>

<sup>3</sup> <http://ilc-congress.eu/>

### *What are the key new treatment recommendations?*

- The policy brief includes three main recommendations:

**1. Patients with HCV infection should be treated with combinations of direct-acting antivirals (DAAs).** In the 2014 guidelines, among other treatments, WHO recommended the use of pegylated interferon in combination with ribavirin for the treatment of chronic HCV infection. In 2016, WHO is recommending that all patients be treated with DAA-based regimens, except for a few specific groups of people in whom interferon-based regimens can still be used (as an alternative regimen for patients genotype 5 or 6 infection and those with genotype 3 HCV infection who also have cirrhosis). The new DAAs recommended in 2016 were selected based on safety, efficacy and acceptability by patients (see below).

**2. Telaprevir and boceprevir should no longer be used.** These two first-generation DAAs, which are administered with pegylated interferon and ribavirin, were recommended in the 2014 guidelines. Evidence now shows that they result in more frequent adverse effects and less frequent cures compared with newer DAA-based regimens. Thus, these two medicines are no longer recommended by WHO.

**2. For the first-time, WHO recommends preferred and alternative DAA regimens based on genotype and cirrhosis status.** The Guideline Development Group reviewed all the available data (over 200 studies) to determine which regimens were most effective and safest to treat each of the six different genotypes. This information was combined with the characteristics of each regimen, such as the treatment duration, pill burden, frequency of drug-drug interactions and requirement for co-administration of ribavirin or interferon, to select preferred and alternative regimens by genotype and cirrhosis status. (The recommended regimens are presented on pages 4-5 of the policy brief.) By providing clear, evidence-based recommendations, this information should facilitate the introduction of HCV medicines in many countries.

- The policy brief also advises policymakers on how to prioritize who should receive treatment in settings where access to treatment is limited. This prioritization is based on two criteria: giving preference to those with advanced disease and those with co-morbidities to maximize the mortality benefit; and to those who are at highest risk of transmitting infection to others (for example people who use drugs) to maximize prevention benefits.

### *How can the new guidelines help?*

- WHO is updating its guidelines based on the latest evidence and science. The new guidelines will enable countries to rationalize their national treatment algorithms to better treat people with chronic hepatitis C infection.
- In a number of countries, the prices of DAAs have come down as a result of price negotiations with the manufacturers and the introduction of generic formulations. The guidelines document will present data that in some countries, DAA-based therapy is actually less expensive than interferon-based therapy.

- For example, in Mongolia it costs an estimated US\$ 900 to give one patient a 12-week course of ledipasvir/sofosbuvir compared with US\$ 5 400 for a 48-week course of pegylated interferon and ribavirin.
- Despite this encouraging development, in many countries the price of the medicines remains a high barrier to the wide-scale expansion of treatment for individuals and national governments.
- WHO calls on all partners and stakeholders to continue intensifying efforts to reduce price barriers that reduce access to these effective medicines. It is anticipated that the new guidelines will help countries make further efforts to enable implementation.

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