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A.31 - Sofosbuvir + velpatasvir (400 mg +100 mg) tablet and (200 mg + 50 mg) tablet

MSF strongly supports the inclusion of both the fixed-dose combinations (FDC) of sofosbuvir + velpatasvir (400 mg +100 mg) tablet and (200 mg + 50 mg) tablet in the core list of the WHO Model List of Essential Medicines for Children (EMLc) in section 6.4.4.2 Medicines for hepatitis C, sub-section 6.4.4.2.1, Pangenotypic direct-acting antiviral combinations, for the treatment of chronic hepatitis C virus (HCV) infection among paediatric patients. As no medicines for hepatitis C are currently included in the WHO Model List of Essential Medicines for Children, these section and sub-section must be created.

Since 2017, the FDC of sofosbuvir + velpatasvir (400 mg +100 mg) tablet is included in the WHO Model List of Essential Medicines (EML), for the treatment of chronic HCV infection in adults. This combination was the first pangenotypic direct-acting antiviral FDC included in the EML.

According to WHO, 71 (62–79) million people worldwide were living with chronic HCV infection and 1.75 (1.57–2.12) million people were newly infected with HCV in 2015. At least 400 000 people died each year, due to liver cancer and cirrhosis caused by untreated HCV infections, 62% of people living with HCV are living in low- and middle income countries (LMICs) and approximately 93% of the people infected with HCV are not receiving treatment. Although the prevalence of chronic HCV infection is lower in children than adults, an estimated 3.5 to 5 million children worldwide have chronic HCV infection.

The 2016 World Health Assembly has adopted targets for the elimination of chronic HCV as a public health threat by 2030. A global elimination strategy cannot succeed unless it includes treatment of children living with chronic HCV infection.

The combination of sofosbuvir + velpatasvir was already included as one of the three recommended pan-genotypic regimens for adults in the 2018 WHO “Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection” and this combination is expected to be added as a treatment regimen for children with chronic HCV infection, for whom dosing recommendations and an appropriate formulation are available, in the 2021 planned update of these guidelines.

The combination of sofosbuvir + velpatasvir, as well as other pangenotypic DAA regimens (glecaprevir + pibrentasvir and sofosbuvir + daclatasvir) presents the advantage of reducing the need for genotyping to guide treatment decisions.

According to a recent systematic review with meta-analysis of clinical trials conducted in children and adolescents, published in 2020, sofosbuvir + velpatasvir is effective for the treatment of all HCV genotypes, in children aged 3 years and older, for whom dosing recommendations and appropriate formulation are available. The good tolerability of this regimen allows a complete treatment course of 12 weeks.

HIV/HCV co-infected children receiving antiretroviral therapy can be treated with the combination of sofosbuvir + velpatasvir, due to its low or manageable risk of drug-drug interactions, except if the antiretroviral regimen includes efavirenz.

MSF would like to draw the attention of the Expert Committee to the following points:

- Since 2020, the two sofosbuvir + velpatasvir FDCs are approved by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA): one daily intake of sofosbuvir + velpatasvir (400 mg +100 mg) tablet for children of 6 years to 12 years of age, weighing 30kg or more; one daily intake of sofosbuvir + velpatasvir (200 mg + 50 mg) tablet for children weighing 17 to 30 kg. MSF would like to emphasize that the (200 mg + 50 mg) FDC is not yet approved by Health Regulatory Authorities for children of 3 years at least and weighing less than 17 kg.

- The two film-coated tablet FDCs of sofosbuvir + velpatasvir are not child-friendly formulations. Again, MSF would like to emphasize that paediatric dosage forms like scored dispersible tablets easily dissolved in water or food should be promoted and should reach internationally agreed quality standards. Access to child-friendly formulations is essential to increase ease and safety of administration as well as adherence to treatment.

- Currently, a single WHO-prequalified generic combination of sofosbuvir + velpatasvir (400 mg + 100 mg) is available but no sofosbuvir + velpatasvir (200 mg + 50 mg) generic is available. MSF would like to emphasize that WHO-prequalified generics should be promoted in order to improve the implementation of affordable sofosbuvir + velpatasvir treatment in LMICs.

- The inclusion of these two sofosbuvir + velpatasvir FDCs in the EMLc will serve as a basis for National Essential Medicines Lists and increase interest in paediatrics formulations. The inclusion will therefore attract additional manufacturers, facilitate importations, alert manufacturers about the need for local registrations, allow for better competition between manufacturers in order to reduce price and thus improve accessibility overall, particularly in LMICs. Therefore, these inclusions will allow to scale-up treatment in children with chronic HCV infection.

- Previously all products listed in the WHO Model List of Essential Medicines for Children were also listed in the WHO Model List of Essential Medicines: if this logic is maintained, sofosbuvir + velpatasvir (200 mg + 50 mg) tablet should also be added in the WHO Model List of Essential Medicines.

Since January 2015, in collaboration with Health Authorities, MSF provided treatments with DAAs to more than 35 800 people living with HCV, in 15 countries.

MSF has been using sofosbuvir + velpatasvir (400 mg +100 mg) tablet in its programs since 2017.

MSF urges the 23rd Expert Committee on the Selection and Use of Essential Medicines to include both the fixed-dose combination of sofosbuvir + velpatasvir (400 mg + 100 mg) tablet and (200 mg + 50 mg) tablet in the EMLc for the treatment of chronic HCV infection in paediatric patient and the fixed-dose combination of sofosbuvir + velpatasvir (200 mg + 50 mg) tablet in the EML.

For Médecins Sans Frontières

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