A.30	Sofosbuvir & Daclatasvir – hepatitis C infection
Does the application adequately address the issue of the public health need for the medicine?	☒ Yes ☐ No ☐ Not applicable Comments: • There are approximately 115 million infected persons in the world. Of these 11 million are younger than 15 years. 80 million are viremic and of these 5 million are younger than 15 years. • Estimated burden of viremic HCV infection in children 1-19 years is 3.5 million (95%CI 3.1-3.9 million). • Largest number of infected children in Asia, Middle East and Africa. • Incidence rising in USA due to opioid abuse • Global health care costs for HCV infected children and their families are hundreds of millions of dollars annually.
Briefly summarize the role of the proposed medicine(s) relative to other therapeutic agents currently included in the Model List, or available in the market.	This combination is approved for use in adults and is included in EML list. The trials for sofosbuvir and daclatasvir in children for genotype 1 & 4. have been conducted in low- and middle-income countries for efficacy and safety.
Have all important studies and all relevant evidence been included in the application?	☒ Yes ☐ No ☐ Not applicable If no, please provide brief comments on any relevant studies or evidence that have not been included:
Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication?	☒ Yes ☐ No ☐ Not applicable Briefly summarize the reported benefits (e.g. hard clinical versus surrogate outcomes) and comment, where possible on the actual magnitude and clinical relevance of benefit associated with use of the medicine(s). • Treatment required only for 12 weeks. • Side effects mild. • Sustained viral response of >95% Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or populations (e.g. children, the elderly, pregnant patients)? YES

Does the application provide adequate evidence of the safety and adverse effects associated with the medicine?	☒ Yes ☐ No ☐ Not applicable Comments:
Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☒ No ☐ Not applicable Comments: monitoring viral load. Liver function tests. Testing for hepatitis B infection prior to starting therapy.
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	Medical benefit is excellent with short term therapy of 12 weeks and SVR >90%.
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	High. The combination of sofosbuvir + daclatasvir has been used in treatment of young children with chronic HCV. Reports of real-world safety and efficacy demonstrate it is a highly effective regimen in children.
Are there any special requirements for the safe, effective and appropriate use of the medicine(s)**?** (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	☒ Yes ☐ No ☐ Not applicable Comments: Check for Hepatitis B infection prior to start of therapy. Monitoring and follow -up of viral load. Liver function tests.
Are you aware of any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	☐ Yes ☒ No ☐ Not applicable Comments:
Is the proposed medicine recommended for use in a current WHO Guideline approved by the Guidelines Review Committee? (refer to: https://www.who.int/publications/who-guidelines)	☒ Yes ☐ No ☐ Not applicable Comments: recommended for chronic HCV infections IN adults

Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	• Accessible. • Generics available. • Cost of treatment not expensive.
Any additional comments	
Based on your assessment of the application, and any additional evidence / relevant information identified during the review process, briefly summarize your proposed recommendation to the Expert Committee, including the supporting rationale for your conclusions, and any doubts/concerns in relation to the listing proposal.	APPROVED for inclusion in EMLc list.
References (if required)	