



**SUBMISSION OF COMMENTS ON THE CLINICAL EVALUATION OF DIRECT ACTING ANTIVIRAL AGENTS INTENDED FOR TREATMENT FOR CHRONIC HEPATITIS C**

EMA/CHMP/EWP/30039/2008

**COMMENTS FROM THE INTERNATIONAL PEDIATRIC TRANSPLANT ASSOCIATION (IPTA)**

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**GENERAL COMMENTS**

The International Pediatric Transplant Association is pleased to be asked to comment on this guideline. Our comments will be limited to potential use of DAAs in pediatric populations. Thank you for allowing us to comment on this thoughtful document.

**SPECIFIC COMMENTS ON TEXT**

**GUIDELINE SECTION TITLE**

<b>Line no<sup>1</sup>. + paragraph no.</b>	<b>Comment and Rationale</b>	<b>Proposed change (if applicable)</b>
4.5.2	IPTA is in agreement with Section 4.5.2 (Studies in Children) and its statements 1. that hepatitis C is not an issue of the same magnitude in children as it is in adults and 2. that clinical efficacy and safety studies in children should be deferred until after data from trials in adults are available. However, it is important to realize that, if data from adult trials are encouraging, once DAAs are available for the indication of treating hepatitis C in adults, then they will undoubtedly be employed in children as well. Thus, IPTA recommends	

<sup>1</sup> Where available

	consideration be given to initiating pharmacokinetic and safety studies in pediatric populations after completion of phase III studies in adults, but prior to final approval of a drug with indications for adult usage.	

Please feel free to add more rows if needed.

These comments and the identity of the sender will be published on the EMEA website unless a specific justified objection was received by EMEA.