



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<Date of submission>

Submission of comments on EMA Consultation: Draft addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements - First version

Comments from:

Name of organisation or individual

British Association of Dermatologists

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).



1. General comments

Stakeholder number <i>(To be completed by the Agency)</i>	General comment (if any)	Outcome (if applicable) <i>(To be completed by the Agency)</i>

2. Specific comments on text

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
		<p>Comment: Point 5.2: Impetigo and infected eczema is seen and studied in adults, so although there are some differences, there may be some information from adult studies that can be extrapolated.</p>	
		<p>Comment: Point 6.2 we have reservations about the ethics of doing placebo controlled studies on impetigo treatment in children. This is a painful and distressing condition that can be treated, so giving placebo in this situation is not ethical.</p> <p>Proposed change (if any):</p>	
		<p>Comment:</p> <p>Proposed change (if any):</p>	

Please add more rows if needed.