

**Eye-Care Industries**  
*European Economic Interest Grouping designate*

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*Please reply to:*

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*Pec/UK*

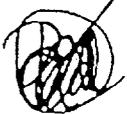
Dear Professor Bass,

**Clinical investigation of medicinal products in the paediatric population  
CPMP/ICH/2711/99 draft**

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Please find attached our comments on this draft guideline.

Yours sincerely,



Brian Matthews.

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24/3/2000	02557	A	☆
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**Clinical investigation of medicinal products in the paediatric population**  
**CPMP/ICH/2711/99 draft**

The document includes a discussion of the circumstances under which specific studies are required for paediatric usage of pharmaceuticals. The list on page 3/12 does not include the route of administration, which may be an important factor for some classes of products such as eye drops and eye ointments.

One important factor to consider here is the low systemic availability likely to result from many ophthalmic products. The ability to undertake pharmacokinetic studies with such products may be limited in any case by the availability of suitable analytical methods even when using the best available technology. The need for and practicality of such studies could be appropriately addressed in the guideline.

Many of the criteria for study according to the draft guideline are designed for oral or other systemic administration routes. It would be helpful to insert a proviso that the omission of such studies should be justified in the case of routes of administration unlikely to achieve significant systemic exposure - eg ophthalmic products.

B R Matthews  
*for the Eye-Care Industries*

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