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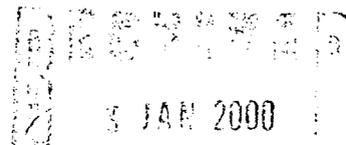
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**From the Chairman of the joint
RCPCH / NPPG Standing Committee on Medicines
Professor Terence Stephenson**

21 December 1999

Dr Julia Dunne
Medicines Control Agency
Room 12-205
Market Towers
1 Nine Elms Lane
London, SW8 5NQ



Dear Dr Dunne

ICH Topic E11: Clinical Investigation of Medicinal Products in Paediatric Age Groups

Thank you for asking the RCPCH / NPPG Standing Committee on Medicines to comment on the above document.

The Committee found much to welcome in the document's recommendations for clinical trials in children and noted that they were broadly in line with those made in the joint BPA / ABPI report, 'Licensing Medicines for Children' (1996).

However the Committee considered that the ICH document would benefit from a more explicit harmonisation with the age ranges recommended in the 1996 report. These are:

Birth to one month
(Subsection: infants under 37 weeks gestation)

One month to ^{two} ~~twelve~~ years

Two to twelve years
(Subsection: under six years old need appropriate formulations)

Twelve to eighteen years.

It was also noted that the document does not clarify the respective roles of the pharmaceutical industry, the licensing authorities and child health practitioners in defining whether a product should be used in paediatric population (para. 1.4) or in the assessment of which products are considered inappropriate (para. 2.1).

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The Committee agreed that 'less than 37 completed weeks of gestation' represents the upper limit of the category 'pre-term infant'. It was also agreed that if members of the Committee had any further comments they would address them directly to yourself.

I hope this is of some value.

Best wishes.

Yours sincerely

A handwritten signature in cursive script, appearing to read "Terence Stephenson".

Terence Stephenson