Short Communication

Medicines for Children

Medicines that are used by members of the European Parliament from all nations undergo formal clinical trials that assess the dose required, efficacy and toxicity. The situation for children and newborn infants, however, is very different. Studies have shown that 67% of children in hospital receive drugs that are prescribed in an unlicensed or off-label manner[1]. [An unlicensed medicine is one which is either not licensed for use in children at all, or has been modified, e.g. a suspension made out of a tablet. An off-label drug prescription is where a medicine is used outside the terms of its product license. Thus a medicine may be used in a different age group or for a different disease than that for which it is licensed.] The situation in the newborn infant is even worse, with 90% of infants in intensive care receiving unlicensed and off-label medicines[2].

There is widespread recognition by health professionals, regulatory authorities and governments that this situation is unacceptable. The licensing process was introduced as a response to drug toxicity after tragedies that affected the developing fetus (e.g. thalidomide) or the newborn infant (e.g. chloramphenicol and the grey baby syndrome). The American government has made legislative changes encouraging pharmaceutical companies to study medicines in children. The American government has also recognised that this is an area where research is limited, and have therefore committed major funding from the US National Institutes of Health to encourage both clinical trials in children and an increase in scientific knowledge on the differences in drug metabolism and mechanisms of action in this age group.

The situation in Europe is very different. A European report on the clinical investigation of medicinal products in children has been published and came into effect in September, 1997. To date, this guidance has had little effect on the study of medicines in children[3]. A European Network for Drug Investigation in Children has been established in order to facilitate both clinical and scientific research into medicines in children[4]. The pharmaceutical industry in Europe has, to date, shown limited interest in this area. We feel it is important that the European community takes a more proactive role in ensuring that (1) research is carried out in this area, (2) that research in this field is prioritised in relation to clinical need and is not left dependent upon market forces and (3) that Europe is not left behind the USA in this important area. Such progress can only be achieved by ensuring legislative changes and funding in this area.

This communication is being submitted by the European Network for Drug Investigation in Children (part of the European Society for Developmental Pharmacology) to all members of the European Parliament and national Ministers of Health.

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References

1. Conroy S, Choonara I, Impicciatore P, Mohn A, Arnell H, Rane A, Knoeppel C, Seyberth H, Pandolfini C, Raffaelli MP, Rocchi F, Bonati M, Jong G, de Hoog M, van den Anker J. Survey of unlicensed and off-label drug use in paediatric wards in European countries. BMJ 2000; 320: 79–82.
2. Conroy S, McIntyre J, Choonara I. Unlicensed and off label drug use in neonates. Arch Dis Child Fetal Neonatal Ed 1999; 80: F142–F145.
3. Impicciatore P, Choonara I. Status of new medicines approved by the European Medicines Evaluation Agency regarding paediatric use. Br J Clin Pharmacol 1999; 48: 15–18.
4. Bonati M, Choonara I, Hoppu K, Pons G, Seyberth H. Closing the gap in drug therapy. Lancet 1999; 353: 1625.