Essential Drugs for Infants and Children: European Perspective

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It is difficult to draw up a list of medicines that are essential for infants and children. It is clear, however, that many of the medicines used appropriately to treat infants and children are not licensed for such use. The medicines concerned may be used outside the terms of their product license, i.e., used off-label, or unlicensed for use in children at any age. Off-label use appears to be a more significant problem than is unlicensed use of drugs in children. Medicines may be used off-label in relation to dose, indication, age, and route of administration.

A helpful way to categorize medicines for children was outlined recently in the European Guidelines on the Clinical Investigation of Medicinal Products in Children. This consists of four separate groups of medicines, as follows:

1. medicines for diseases affecting children exclusively;
2. medicines intended to treat diseases that primarily affect children or are of particular gravity in children, or have a different natural history in children;
3. medicines intended to treat a disease occurring in adults and children, for which there is currently no treatment; and
4. medicines intended to treat a disease occurring in adults and children, for which treatment exists.

Of these four categories, medicines within the first three all are essential for children. These guidelines are to be beneficial, and pharmaceutics companies are to be encouraged to conduct clinical trials within these areas. For many of the medicines currently being used in children, there is inadequate data in relation to efficacy and toxicity. It is essential that controlled clinical trials are conducted, evaluating both efficacy and toxicity in children of different age groups and different disease states.

The evaluation of the efficacy of medicines in young infants and children may involve the development of appropriate drug assessment tools. This is illustrated through an analysis of the areas of pain and sedation. Analgesia and sedation are as essential for infants and children as for adults. In infants, they are most important because the infant does not have the comprehension whereby a procedure can be explained as likely to cause pain. The development of appropriate age-related pain assessment tools, such as the Liverpool Infant Distress Score or the Neonatal Infant Pain Scale, is necessary to evaluate different analgesic agents. Sedation is essential in critically ill infants and children, and yet the assessment of the level of sedation and the efficacy of sedative drugs, which invariably are used off-label, have been evaluated only recently. These studies show that medicines that are routinely used can be evaluated and that such trials are essential.

If one is considering essential drugs for infants and children, the formulation must be recorded. For infants and young children, a solution or suspension is required because they are unable to take either tablets or capsules. This is a problem with medicines used infrequently in infants and children and, therefore, it is not profitable to produce a suitable formulation. In such situations, parenteral formulations often are used off-label and given orally.

There have been major advances in relation to different types of inhalers for children of different ages with asthma, such as the turbohaler, nebuhaler, and volumatic inhaler. This is beneficial and results from the fact that there is a large market for asthma treatment for children.

The development and evaluation of essential drugs for infants and children require collaboration among pediatricians, pharmacists, the pharmaceutics industry, and regulatory authorities.

REFERENCES

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