COMMENTS ON APPLICATION FOR INCLUSION OF ORAL IBUPROFEN SUSPENSION ON WHO MODEL LIST OF ESSENTIAL MEDICINES 2005

Background

Ibuprofen is on the WHO EML as a tablet but not suspension/liquid. This application is from the International Ibuprofen Foundation. This group makes the following statement on their website: “The International Ibuprofen Foundation (IIF) has been established by a group of companies with international interests in analgesic products based on ibuprofen, with particular reference to self-medication.” This product was previously considered by the Essential Medicines committee in 2003 and the application declined. (http://www.who.int/medicines/organization/par/edl/expcom13/expcom03add.shtm)

The application

The authors undertook a comprehensive literature review across a wide range of databases looking to randomised controlled trials, systematic reviews and meta-analyses. This looked for studies in children aged <16yrs receiving either ibuprofen or a comparator for fever. The search strategy seems to be of a good standard.

The results are presented in a table of included studies however type of study is not made clear in the table and other literature such as narrative reviews seem to have crept in.

The majority of studies listed are single dose and while some 25 studies (?RCTs) are tabulated published systematic reviews only cover a proportion of these. The authors did not present a results summary or provide analysis in terms of an overall estimate of effect- this is a significant omission. Some data is presented on adverse effects (AEs) however single dose studies will underestimate AEs as the exposure to treatment is so short.

Data is also presented on comparative costs based on the International Drug Price indicator guide. Ibuprofen is slightly more expensive than an equivalent dose of paracetamol elixir.

Conclusions and Recommendations

The application falls short in terms of providing clear and concise evidence to enable the committee to make a decision. There is data to show that ibuprofen is effective and in occasional acute use safe. There is already provision on the EML for the treatment of fever in children namely paracetamol elixir. No clear case has been made for the benefits of Ibuprofen over the existing provision on the EML and I recommend that the ibuprofen suspension should not be added to the EML.

P. Wiffen
Cochrane Pain and Palliative Care Group
Jan 7th. 2005