

Comments on essential medicines for children

It is stated in the first draft of WHO Model List of Essential Medicine for Children Explanatory notes that comments on the draft should be submitted no later than 31 May 2007. Full proposals for additional medicines should be made no later than 15 May 2007.

I, therefore, keep the deadline of comments on the draft, 31 May 2007.

These comments were made based on documents provided in the website linked. There are 5 main documents available on the website, i.e. 1) criteria for selection of essential medicine, 2) position paper on preferred dosage forms to be included in a Model Essential Medicines List for Children, 3) position paper: paediatric age categories to be used in differentiating between listing on a Model Essential Medicines List for Children, 4) report on adherence to medications in children, and 5) first draft: WHO Model List of Essential Medicines for Children Explanatory notes.

1) Criteria for selection of essential medicine, in the box:

Para 1

- **disease burden:** it should be given more definition in children. Whether DALY could be applied for infant, or high incidence, less incidence but fatal, for example.
- **Efficacy and safety and comparative cost-effectiveness:** Probably, there is rare data in children since ethical issue is much concerned in clinical trials in children. In US FDA, approval indications and test data and clinical data in children are required and the companies will get exclusive right from data exclusivity.

Para 3

- **The cost of the total treatment and unit cost** are mentioned. Such cost should be more clarified that which cost will be included e.g. direct medical care cost.
- **Cost and cost-effectiveness comparisons may be made among alternative treatment within the same therapeutic group.** This means including comparison of different pharmacological group? If yes, drugs should be evaluate through the treatment guideline accordingly, in particular to the anti-infective drugs which will be used as first line, second line drug. Drugs should be compared within the same level of choice.

2) Position paper on preferred dosage forms to be included in a Model Essential Medicines List for Children

Introduction

- **Bioavailability of selected drug form:** it is mentioned that it must be assured. **Could each form be tested in children or this will be referred to adult data?**
- Oral formulation

- Factor to consider choosing...

- Tablets should be scored for easily split: **there are certain sorts of tablets which can be split. For example, some form of sustain release could not be divided. Thus this tablet should be described as separable tablet.**
- Apart from spoon, **dropper and syringe are used as well.**
- Water used to suspend or dilute tablet: besides free of contaminants and pathogen water. **Practically boiled water which is cool down to room temperature is used.**

- Factor to consider in choosing a liquid formulation

- In addition to sorbitol and xylitol, **all formulations (suspension and solution) used in children should be free from alcohol.**
- **Flavor should be selected according to pharmaceutical technology in terms of, for example, physicochemical compatibility.** Then favor selected should have been...without risk of adverse effect.

- **Drugs in all formulation should be available in a protected from light container if needs.**

- Parenteral formulations

- Factors...

- Formulation should be available in a protected from light containers **if needs**
- Tear off label from original vial to label syringes for patient safety. **This is not applicable in Thailand.**

- Injectables

In choosing...

- The product should be compatible with glucose 5% & 10%, sodium chloride 0.18%(N/5), 0.22%(N/4), 0.3(N/3), 0.45%(N/2) and 0.9%...**These strength are also used in children.**

- The maximum rate of administration should be stated in mg/Kg/minute or microgram/Kg/minute **in what? ..patient information leaflet or else? This label should be stuck on drug container during administration.**

Policy statement: Wherever possible, the intramuscular route of drug administration should be avoided. **In practice, most of EPI vaccine is given by intramuscular or subcutaneous injection.**

3) Position paper: Paediatric age categories to be used in differentiating between listing on a model essential medicines list for children

This paper describes two concepts of children age subcategories. It is said to be discussed in the meeting.

4) Report on adherence to medications in children

This report is a literature review, therefore, it provides knowledge about patients' adherence.

5) First draft: WHO Model list for essential medicines for children

This list will take more time to find evidence and reference for suggestion on drug addition or deletion. It needs expertise.