Federal Agency for Medicines and Health Products

FAMHP POSITION ON ETHANOL CONTENT IN MEDICINAL PRODUCTS USED IN CHILDREN (including herbal medicinal products and homeopathic medicinal products)

It is unrealistic to expect studies where safety thresholds for ethanol content in medicinal products intended for paediatric use are directly demonstrated. The evaluation must stand on other bases.

Taking into account:

- not only the normal use of a product but also the potential accidental intake by children of different ages,
- the fact that the speed of metabolism of ethanol and the distribution volume in children varies with age,
- the use of ethanol containing preparations in children should be limited as much as possible,

the following recommendations should be made:

- Ethanol administration to children should be minimised and the benefit/risk -ratio should be judged keeping in mind the target population. All medicinal products containing ethanol, are should not be used in neonates and infants below 2 years unless adequate justification is given.
- The concomitant use of multiple medicinal products that contain ethanol should be avoided.
- The dose interval should be kept as long as possible, however it should be at least 4 hours to avoid accumulation. The whole treatment period should be as short as possible. For children below 6 years of age, adequate justification must be provided if the treatment exceeds one week.
- Appropriateness and safety of alternatives to ethanol should be considered and continued efforts should be made to have ethanol replaced in preparations intended for paediatric use.
- Harmful impairment of psychomotor functions can already occur when blood ethanol concentration is above 0.125 g/L. Therefore, the recommendation is that a 0.125 g/L blood ethanol concentration should not be exceeded following a single dose of medicinal product containing ethanol
- A childproof closure is recommended for medicinal products with an ethanol content greater than 5%. The need for a childproof closure should however not only be related to the concentration but also to the total amount of ethanol present in the medicinal product. A childproof closure is required for containers that contain amounts of ethanol that could produce a blood ethanol concentration greater than 1g/l, when accidentally ingested as a whole.
- Information regarding the ethanol content of the medicinal product should be provided in a clear and explicit manner in the package leaflet.

For homeopathic medicines the concentration of ethanol can be reduced by mixing the dose in a quantity of water and giving the mixture in a timeframe of several hours. This should be reflected in a recommendation for the correct use in the leaflets.

- Interactions for combinations / concomitant medications likely to be used in paediatric population should be taken into account. Ethanol may enhance the absorption and pharmacological effect of some drugs, such as sedatives, and affect the elimination of others by inducing and/or inhibiting the cytochrome P450-dependent elimination pathways. In addition, ethanol may, in the presence of, e.g., some antibacterials, cause a disulfiram-like reaction.
  Administration of drugs containing ethanol in children should/must be subject to prior medical evaluation, in particular to check for the lack of contraindications/interactions, unless justified.