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Press Office

Press release

European Medicines Agency concludes review of dose recommendations for anti-tuberculosis medicines used in children

Agrees with WHO recommendations for ethambutol, isoniazid, pyrazinamide and rifampicin

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded its review of dosing recommendations from the World Health Organization (WHO) for first-line anti-tuberculosis medicines in children.

While the Committee acknowledged that the dosing regimen of first-line anti-tuberculosis therapies is difficult to define in children due to the limited data available and several other influencing factors, it agreed with the WHO dosing recommendations for ethambutol, isoniazid, pyrazinamide and rifampicin for children above three months as follows:

Ethambutol:	20 (15-25) mg/kg
Isoniazid:	10 (10-15) mg/kg
Pyrazinamide:	35 (30-40) mg/kg
Rifampicin:	15 (10-20) mg/kg

The Committee acknowledged the WHO conclusion that no dosing recommendation can be made in children less than three months due to the lack of specific data.

The review was triggered in 2011 by the French medicines agency, following the publication of pharmacokinetic data on use of anti-tuberculosis medicines in children, which showed that weight-based dosing regimens based on corresponding adult weight might lead to sub-optimal exposure in children. The issue was recognised by the WHO in 2008, which subsequently recommended changes to dosing. The review did not address multi-resistant tuberculosis.

The review aims at optimising therapeutic management of the disease in the European Union and harmonising dosing in order to encourage the development of fixed dose combinations (FDC) by pharmaceutical companies. FDCs are important as they can improve how well a patient is able to follow

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medical advice in terms of taking medicine at the right time and taking the correct number and combination of tablets. This can be especially challenging with children.

While most cases of tuberculosis are limited to developing countries the disease is still prevalent in some European Member States. The average notification rate for tuberculosis in the European Union (EU) and European Economic Area (EEA) region is 16.7 per 100 000 population (2008 data).

This CHMP opinion will be communicated to the European Member States, so that they can take appropriate action at national level.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. All other opinions and documents adopted by the CHMP at its February 2012 plenary meeting will be published on Friday, 17 February 2012 at 12.00 noon UK time on a dedicated webpage.
3. The review of anti-tuberculosis medicines is being conducted in the context of a formal review under Article 5(3) of Regulation (EC) No 726/2004. The assessment report for this procedure will be published in the coming weeks on the Agency's website.
4. See more information on tuberculosis on the website of the European Centre for Disease Prevention and Control (ECDC).
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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