EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency gives first positive opinion for paediatric-use marketing authorisation

Buccolam recommended for treatment of prolonged, acute, convulsive seizures in paediatric patients from 3 months to 18 years

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has given its first positive opinion for a paediatric-use marketing authorisation (PUMA) for Buccolam (midazolam), from ViroPharma SPRL, intended for the treatment of prolonged, acute, convulsive seizures in paediatric patients from the age of 3 months to 18 years.

Paediatric-use marketing authorisations were introduced by the paediatric legislation. They can be granted for medicines which are already authorised, but no longer patented, and which will be developed specifically for children. These medicines benefit from 10 years of market protection as an incentive.

Prerequisite for a PUMA is a paediatric investigation plan (PIP) which sets out the development of the medicine in children and has to be approved by the Agency's Paediatric Committee (PDCO). Compliance with the PIP has to be verified before the start of the authorisation procedure.

The PIP for Buccolam was approved on 11 August 2009.

Dr Agnès Saint-Raymond, Head of Human Medicines Special Areas at the European Medicines Agency said: "We welcome this first opinion for a PUMA. Since the coming into force of the Paediatric Regulation in 2007 companies have given too little attention to the incentives for paediatric-use marketing authorisations. I am pleased to see that ViroPharma SPRL has dedicated its resources to conduct specific paediatric studies and to develop a paediatric formulation for all paediatric age groups from 3 months to 18 years of age in acute seizures, a disease that affects children and the elderly."

In the past, many medicines authorised in Europe were not studied adequately or authorised in children. This caused difficulties for prescribers and pharmacists treating children, as well as for their patients and carers.

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A dedicated development of established medicines in children ensures that prescribers can base their treatment on adequate information on the efficacy and the safety of a medicine and prescribe the correct dose and use the appropriate pharmaceutical form.

As of today 26 applications for PIPs for PUMAs have been received by the Agency and 7 opinions have been given by the PDCO.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The decision for the PIP of Buccolam dated 11 August 2009 is available on Agency's website.
3. The summary of opinion for Buccolam is available on the Agency's website.
4. A paediatric use-marketing authorisation according to Article 30 of Regulation (EC) No. 1901/2006 may be requested for a medicine which is already authorised, but no longer covered by intellectual property rights (patent, supplementary protection certificate), and which will be exclusively developed for use in children. This type of marketing authorisation will cover the indication and appropriate formulation for the paediatric population. The development of this medicine in children will follow a paediatric investigation plan which must discuss all paediatric subsets.
5. More information on paediatric-use marketing authorisations is available on the Agency's website.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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