European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency makes first recommendation for use of a medicine in children based on PIP data

The European Medicines Agency (EMEA) has made its first recommendation for the use of a centrally-authorised medicine in children on the basis of clinical trial data generated in accordance with an agreed paediatric investigation plan (PIP). This is the first example of the changes brought in by the Paediatric Regulation benefiting children in Europe.

PIPs are one of the tools created by the Paediatric Regulation as part of the drive to improve the health of children in Europe. PIPs are drug-development plans that set out measures ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of the medicine for children. PIPs must be agreed in advance by the Agency's Paediatric Committee (PDCO), and are legally binding for companies developing medicinal products for use in the European Union (EU).

Using the data generated as part of a PIP, the marketing authorisation holder for Cancidas (caspofungin), a medicine already authorised for the treatment of adults with severe fungal infections, applied for an extension of indication for use in children. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the data on the quality, safety and efficacy presented support this extension of indication.

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Notes:

1. The Paediatric Regulation is Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use. More information about the Paediatric Regulation is available on the 'medicines for children' section of the Agency's website: http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm
2. More information on Cancidas, including its current indication, is available in the European Public Assessment Report (EPAR) on the Agency's website: http://www.emea.europa.eu/humandocs/Humans/EPAR/cancidas/cancidas.htm
3. The European Medicines Agency adopted a decision on the PIP for Cancidas in February 2008 and a modification of the PIP in May 2008. The Decision on the PIP for Cancidas can be found here: http://www.emea.europa.eu/pdfs/human/paediatrics/9658708en.pdf. The Decision on the modification of the PIP can be found here: http://www.emea.europa.eu/pdfs/human/paediatrics/000010-PIP01-07-M01.pdf
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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