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Press Office

Press release

European Medicines Agency gives first opinion on compassionate use

The Agency's Committee for Medicinal Products for Human Use (CHMP) has given its first opinion on the compassionate use of a medicine. Compassionate use programmes are intended to give patients with a life-threatening, long-lasting or seriously disabling disease, who have no available treatment options, access to treatments that are still under development and that have not yet been authorised.

A CHMP opinion on a medicine intended for compassionate use provides recommendations to all European Union (EU) Member States. It describes which patients may benefit from the medicine, explains how to distribute and use the medicine and gives information on safety.

The implementation of these recommendations within the individual Member States is not mandatory, but Member States can consider them when setting up compassionate use programmes.

The European Medicines Agency is publishing a list of opinions on the compassionate use of medicines adopted by the CHMP on its website.

This first CHMP opinion on compassionate use was based on a request from Finland. It relates to an intravenous formulation of oseltamivir, Tamiflu IV, to treat critically ill patients with a life-threatening condition due to suspected or confirmed pandemic or seasonal flu, who cannot take authorised antivirals by mouth or as an inhalation.

Oseltamivir is already authorised in the EU as Tamiflu for oral use. Usually authorised medicines are excluded from compassionate use programmes. However, Tamiflu IV, which is not authorised, is a new development for intravenous use and for a new target population. The currently available pharmaceutical, pre-clinical and clinical data are very limited. The Agency will evaluate all relevant information that becomes available and update this compassionate use opinion as appropriate.

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Notes

1. CHMP Opinions on compassionate use are based on article 83 of Regulation (EC) No 726/2004, see here: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf

2. A separate question-and-answer document on the compassionate use of medicines in the EU is available here: http://www.ema.europa.eu/pdfs/human/euleg/7214406enfin.pdf.pdf

3. For more information see the compassionate use section of the Agency's website here: http://www.ema.europa.eu/htms/human/compassionate_use/compassionate_use.htm

4. The conditions of use, conditions for distribution, target population and conditions for safety monitoring addressed to Member States for compassionate use of Tamiflu IV are available here: http://www.ema.europa.eu/pdfs/human/compassionte_use/4556610en.pdf

5. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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