



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 August 2013
EMA/480494/2013

Public statement

Public statement on Tamiflu IV

Closure of compassionate use programme in the European Union

On 10 June 2013, the manufacturer for Tamiflu intravenous (IV), F. Hoffmann-La Roche Ltd., informed the Agency's Committee for Medicinal Products for Human Use (CHMP) of its decision to close the compassionate use programme for Tamiflu IV.

In January 2010, the CHMP adopted a positive opinion to make Tamiflu IV available to treat critically ill patients with a life-threatening condition due to suspected or confirmed pandemic or seasonal flu, who could not take authorised antivirals by mouth or as an inhalation.¹ Tamiflu IV was a new formulation of the medicine Tamiflu, which was being developed for intravenous use.

In its letter² notifying the Agency, the manufacturer provided as reason for the closure of the compassionate use programme the low number of participants in the most recent pandemic season. In addition, F. Hoffmann-La Roche Ltd. stated that following its decision to close down clinical studies involving Tamiflu IV, it was no longer seeking authorisation of the product. There are no concerns with respect to the safety and efficacy of Tamiflu.

The compassionate use programme for a similar antiviral medicine continues.

¹http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2010/01/news_detail_000986.jsp&mid=W0b01ac058004d5c1

²http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/08/WC500148370.pdf

