

Product and Application Business Support  
(V-PD-BUS)  
European Medicines Agency  
Ontario Way  
Canary Wharf  
E14 4HB London  
United Kingdom

cc: [REDACTED] (Clinical PTL)  
Dr Outi Mäki-Ikola (Rapporteur)  
Prof. Bruno Sepodes (Co-rapporteur)  
All CHMP Members

**Subject:**

**Tamiflu® (oseltamivir phosphate) IV Compassionate Use (CU) Programme - EMEA/H/K/002287  
Closure of Programme**

Basel, 10 June 2013

Dear Ladies and Gentlemen,

We wish to inform you that we are closing down the Tamiflu IV CU Programme by 30 June 2013.

The requests to participate in the IV CU Programme have shown a steady decline since the pandemic, numbering only 10 in the most recent season. Following our decision to close down IV clinical studies with the result that we would not seek registration for this formulation, Roche no longer has any clinical or technical development work ongoing to support the IV formulation. Consequently neither replenishment of supply or provision of a definitive dosing recommendation will be possible, hence the decision to close the programme at this time.

Moreover, as development work and an associated CU programme continue for another neuraminidase inhibitor we believe the needs of the few patients requiring this formulation can be met.

**Roche Registration Limited**

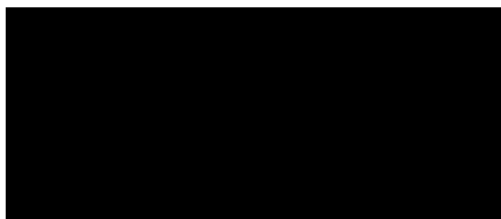
[REDACTED]  
Head, EU/ROW Regulatory Affairs,  
Roche Registration Limited,  
6 Falcon Way, Shire Park,  
Welwyn Garden City,  
AL7 1TW United Kingdom.  
Phone: [REDACTED]  
Fax: +44 (0) 1707 384142

reply to: [REDACTED]  
F. Hoffmann-La Roche Ltd  
CH-4070 Basel  
Switzerland  
Tel: [REDACTED]  
Fax: +41 61 688 1560  
Email: [REDACTED]

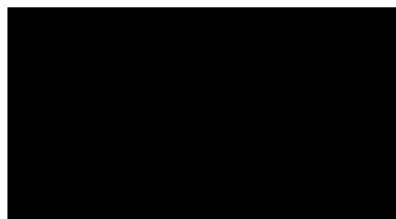
A report on the limited safety data from the IV CU Programme and the clinical study reports from the halted clinical trials will be sent to you in due course.

Should you have any questions or require any further information, please do not hesitate to contact us.

Yours sincerely,  
F. Hoffmann-La Roche Ltd



Tamiflu International Medicinal Leader



Regulatory Program Manager