ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented.

The Member States shall ensure that the MAH provides all physicians who are expected to prescribe or use Tamiflu a Direct Healthcare Professional Communication (DHPC) letter, the text of which is appended to the CHMP assessment report. The Member States shall agree with the MAH the communication plan for the DHPC letter.