Pandemic Dossier requirements

Existing requirements (recipients etc) pertaining to the formal submission of MAAs and all post-approval procedures to the CHMP and EMEA remain unchanged for the purpose of pandemic dossier submissions unless otherwise specified in the tables below. Although requirements for paper and electronic copies are given below, where considered necessary by the EMEA, the clock will start upon receipt of the electronic documentation.

Formal submission of Pandemic Type II variation*		
CHMP	EMEA Product Evaluation Team (EPT)*	EMEA
Existing submission requirements apply for paper copies. 1 electronic copy	1 paper copy 1 full electronic copy	Existing submission requirements apply for paper copies. 1 full electronic copy sent to the central information group **

Interim submissions* **e.g. Submissions of data for ETF review***	
ETF	EMEA
1 paper copy 1 electronic copy	2 Paper copies sent to central information group. 2 full electronic copies sent to the central information group, Product team Leader and Product team Member*

Formal submission of MA during a pandemic *		
CHMP	EMEA Pandemic Task Force (ETF)**	EMEA
Existing submission requirements apply for paper copies. 1 electronic copy	1 paper copy 1 full electronic copy	Existing submission requirements apply for paper copies. 2 full electronic copies sent to the central information group **

* The tables relate to initial submissions and also responses (except for responses submitted for the pandemic variation since the evaluation timetable is 4 days. Any responses submitted during this time period will need to be submitted electronically. Any deviation from the requirement to submit paper copies for responses should otherwise be agreed with the EMEA Product team leader.

**For explanation of the ETF and EPT groups see http://www.emea.eu.int/pdfs/human/veg/498603en.pdf - Guideline on Submission of MAAs for pandemic influenza vaccines through the centralised procedure and related SOPs. Lists of ETF, EPT members, Product Team leaders and Product team members for respective products will be provided to the Companies concerned during pre-submission discussions with the EMEA.

*** These interim submissions refer to the activities described in the work instructions to the EMEA Crisis Plan.

Relevant hyperlinks for general submission requirements

http://www.emea.eu.int/htms/human/presub/q23-1.htm http://www.emea.eu.int/htms/human/presub/q23-2.htm

http://www.emea.eu.int/htms/human/presub/q24.htm http://www.emea.eu.int/htms/human/postguidance/list.htm