



Title: Glossary of terms used in Work Instructions in Annex I of the EMEA Influenza Crisis Management Plan		
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Signature: On file	Signature: On file	Effective Date: 20-SEP-06
Date: 20-SEP-06	Date: 20-SEP-06	Supersedes: n/a

**A**

ADR	Adverse drug reaction
AR	Assessment report

**B**

BCP	Business Continuity Planning
BWP	CHMP Biologics Working Party

**C**

CD	Commission Decision
CHMP	Committee for Medicinal Products for Human Use
CIG	EMEA Central Information Group
CMD(h)	Coordination Group for Mutual Recognition and Decentralised Procedures (human products)
Crisis Teams	In order to react promptly, in case of an influenza pandemic, the following EMEA crisis teams are established, namely: a. Gold team b. Pandemic Silver Crisis team c. Pandemic Bronze Crisis team Refer to the EMEA Pandemic Influenza Crisis Management Plan (EMEA/214301/2006) for the composition and role of crisis teams.

**E**

EC	European Commission
ECD	Eudra Common Directory
ED	EMEA Executive Director
EDMS	Electronic document management system
EDQM	European Directorate for the Quality of Medicines
EMEA	European Medicines Agency
ENTR	European Commission's Directorate-General for Enterprise and Industry
EPAR	European public assessment report
EPT	Evaluation Project Team (for a pandemic influenza vaccine application) Refer to the EMEA Pandemic Influenza Crisis Management Plan (EMEA/214301/2006) for the composition and role of EPT.
ES	EMEA Executive Support Sector
ETF	EMEA Task Force (for Pandemic Influenza) Refer to the EMEA Pandemic Influenza Crisis Management Plan (EMEA/214301/2006) for the composition and role of ETF.
EU	European Union
EVM	European Vaccine Manufacturers (specialised group within EFPIA)

<b>F</b>	
FDA	Food and Drug Administration (United States of America)
FUM	Follow-up measure

<b>G</b>	
GMO	Genetically-modified organism
GMP	Good Manufacturing Practice

<b>H</b>	
HoA	Heads of Agencies
HoS	Head of Sector
HoU	Head of Unit

<b>I</b>	
IPM	Influenza Pandemic Manual
IS	EMEA Inspections Sector
ISERV	EMEA Infrastructure Services Sector
IT	EMEA Information Technology Sector

<b>J</b>	
JEIF	<p>Joint EMEA Industry Task Force - JEIF will meet at regular intervals during the interpandemic period and at the latest during phase 5 of the pandemic alert period. The composition of the JEIF is the following:</p> <p><u>Core members:</u></p> <ol style="list-style-type: none"> <li>1. Industry participants: representatives from the influenza vaccine manufacturers and from EVM</li> <li>2. Authority representatives <ol style="list-style-type: none"> <li>a. Rapporteurs / Co-Rapporteurs of core dossiers, or in absence of submitted core dossiers, appointed CHMP members</li> <li>b. Chairpersons of the Vaccine Working Party, the Ad-Hoc Influenza Working Party, BWP and PhVWP</li> <li>c. Members of the VWP and Ad-hoc influenza Working Party</li> <li>d. Representatives of Commission (ENTR, SANCO)</li> </ol> </li> <li>3. EMEA Secretariat Staff</li> </ol> <p><u>Additional members:</u></p> <p>Depending on the agenda of the meeting, the following will be invited:</p> <ul style="list-style-type: none"> <li>- Members of the GMP inspectors working party and/or GMP inspectors from the supervisory authorities</li> <li>- Representative from OMCL/EDQM</li> <li>- Representative from WHO</li> <li>- Additional experts, e.g. on GMO or patent issues</li> </ul> <p><u>Chairpersons:</u></p> <p>A chairperson and co-chairperson are elected from the Authority representatives and Industry participants respectively.</p>

<b>L</b>	
Legal Affairs	EMEA Legal Affairs Sector
LOQ	List of Questions

<b>M</b>	
MA	Marketing authorisation
MAA	Marketing authorisation applicant

MAH	Marketing authorisation holder
MI	EMEA Medical Information Sector
MM&C	EMEA Meeting Management and Conference Sector

<b>O</b>	
OIE	World Organisation for Animal Health
OMCL	Official Medicines Control Laboratory (of a European Economic Area Authority)

<b>P</b>	
PASE	EMEA Post-Authorisation Safety & Efficacy Sector
PhVWP	CHMP Pharmacovigilance Working Party
PIT	Pandemic Intelligence Team PIT will screen on a daily basis, for information published on official Websites (e.g. WHO, OIE, Commission) and in the press related to pandemic influenza. This information will be evaluated, and any signals indicative of an increase in pandemic alert level, or an imminent announcement of an influenza pandemic, will be cross-checked, promptly, with dedicated contacts at the European Commission (SANCO) and/or at WHO or WHO collaboration laboratories. Confirmed signals will (via Head of Sector, Quality of Medicines) be brought to the attention of the EMEA Gold Team.
PL	Package Leaflet
Post	Post-authorisation Evaluation of Medicines for Human Use
PSUR	Product safety update report
Pre	Pre-authorisation Evaluation of Medicines for Human Use
PTL	Product Team Leader All PTLs are assigned from the bronze team. All initial activities described in work instructions are undertaken by a PTL Q. However, at IPM stage 6.0 (WIN/H/3083), the EMEA Pandemic Silver team will re-assign products to various PTLs from the pandemic bronze team. The PTL may subsequently be from Q, S&E or PASE, depending on workload. In this case, the PTL S&E or PTL PASE must ensure that their respective PTM Q is kept informed of activities on an on-going basis. The PTM Q will update Q sector, which retains overall co-ordination of pandemic vaccine activities.
PTLS	Product Team Leader Secretary
PTM	Product Team Member (S&E, Q or PASE) All PTMs are assigned from the bronze team.

<b>Q</b>	
Q	EMEA Quality of Medicines Sector
QRD	Quality review of documents

<b>R</b>	
RA	EMEA Regulatory Affairs Sector

<b>S</b>	
SANCO	European Commission's Directorate-General for Health and Consumer Protection
S&E	EMEA Safety and Efficacy Sector (Pre-authorisation)
SO	Specific obligation
SOP	Standard Operating Procedure
SPC	Summary of product characteristics

<b>T</b>	
Telecon	Telephone conference
TFR	EMA Pandemic Task Force report
TGA	Therapeutic Goods Administration (Australia)

<b>U</b>	
UK	United Kingdom
USR	Urgent safety restriction

<b>V</b>	
VWP	CHMP Vaccine Working Party

<b>W</b>	
WHO	World Health Organisation
WHO phases	<p>Phases before and during an influenza pandemic, as described in the <i>WHO global influenza preparedness plan</i> (WHO/CDS/CSR/GIP/2005.5) published in April 2005.</p> <ul style="list-style-type: none"> <li>- <u>Phase 1 and 2</u> are phases in the interpandemic period, with no new virus subtypes being detected in humans</li> <li>- <u>Phase 3 to 5</u> are phases in the pandemic alert period: <ul style="list-style-type: none"> <li>a. Phase 3: Human infection(s) with a new subtype, but no human-to-human spread, or at most rare instances of spread to close contact</li> <li>b. Phase 4: Small cluster(s) with limited human-to-human transmission but spread is highly localised, suggested that the virus is not well adapted to humans.</li> <li>c. Phase 5: Larger cluster(s) but human-to-human spread still localised, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk).</li> </ul> </li> <li>- <u>Phase 6</u>: Pandemic period: increased and sustained transmission in the general population.</li> </ul>
WIN	Work Instructions