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EMEA PANDEMIC INFLUENZA CRISIS MANAGEMENT PLAN FOR THE EVALUATION AND MAINTENANCE OF PANDEMIC INFLUENZA VACCINES AND ANTIVIRALS

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Note	Annex I to this Plan (<i>EMEA Pandemic Influenza Process map</i>) is also released for consultation. The associated Work Instructions referred to in this Annex are available on request.
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Annex 1 **EMEA pandemic influenza process map and associated Working Instructions and SOPs dealing with the EMEA responsibilities for influenza pandemic – integration of the activities of review, post-authorisation activities, communication, meetings, telecommunications.**

Annex 2 **List of all crisis contact points within the EMEA**

Annex 3 **List of all crisis contact points within the Commission and other Agencies**

Annex 4 **List of all crisis contact points within the Member States**

Annex 5 **List of all crisis contact details of Rapporteurs, CoRapporteurs and assessors of pandemic influenza vaccines**

Annex 6 **List of all crisis contact points within the Industry**

I. INTRODUCTION

The *EMEA Pandemic Influenza Crisis Management Plan for the evaluation and maintenance of pandemic influenza vaccines and antivirals* (“EMEA Pandemic Influenza Crisis Plan”) outlines the policy, strategy and procedures to be followed:

- for fast-track approval of pandemic influenza vaccines via the centralised procedure;
- for post-authorisation follow-up of centrally authorised pandemic influenza vaccines and antivirals;
- to react to any safety signals arising from the use of non-centrally authorised antivirals or from the use of bulk active substance of centrally authorised antivirals.

The plan highlights, also, the required management structures and the detailed procedures to be set up to support the various associated processes.

The EMEA Pandemic Influenza Crisis Plan will allow the EMEA to respond rapidly, and efficiently, when a pandemic influenza crisis is announced. The crisis plan will be validated and tested with possible crisis scenarios, reviewed and regularly updated. The proposal is to undertake these activities in the first quarter 2006.

The EMEA activities described in this plan will run in parallel with Business Continuity Planning (BCP) activities invoked by the pandemic influenza crisis. These BCP activities are not described in this plan¹.

II. PRINCIPLES OF THE CRISIS MANAGEMENT PLAN

- The primary objective of the crisis management plan is to define and implement the EMEA policy and, consequently the strategy for the rapid and efficient handling of actions required by the EMEA Secretariat related to pandemic influenza vaccines and antivirals, in liaison with the CHMP, (Co-) Rapporteurs, competent authorities of the Member States, the European Commission (DG Sanco and DG Enterprise) and the Marketing Authorisation Holders, or Applicants.
- The WHO will identify the start of the influenza pandemic. This information will be provided to the Commission (DG Sanco) who will notify the EMEA. It will require the EMEA to work with all of the interested parties cited above in reviewing variations to core dossiers for influenza pandemic vaccines and / or the review of dossiers submitted to the Agency, for medicinal products falling within its responsibilities.
- A procedure has been developed on surveillance and how the start of a pandemic will be recognised and communicated, so that the implementation of the crisis management plan may be initiated promptly.
- A management procedure is presented in this crisis plan on how the announcement of the pandemic will trigger the EMEA pandemic plan as discussed in the process map (Annex 1) and underlying work instructions and SOPs.
- In the event of a pandemic, the public will be aware of the situation in a similar time frame to the Commission, Member States and the Agency, thus the handling of communications will become crucial especially when public confidence is at risk. EMEA communication policy on this aspect will be in place to deal with the matters within its remit, taking care of the interface

¹ BCP activities are covered by the general SOP on EMEA Business Continuity Planning.
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and roles and responsibilities of other interested parties, including the Commission, the ECDC and Member States.

- Lists of all crisis contact points within the EMEA, Commission and other Agencies, Member States and Industry and contact details of Rapporteurs, CoRapporteurs and assessors of pandemic influenza vaccines are provided at Annexes 2 to 6.

III. KEY OBJECTIVES OF THE PROCEDURE TO BE FOLLOWED

III.A. Handling of a crisis situation in case of influenza pandemic

In addition to the management teams and systems put in place at the level of the EMEA and with other interested parties, the aim is to meet the following key objectives, which are to:

- Initiate the influenza pandemic plan and activate all parts of the network and to co-ordinate the different activities between the interested parties as described in the pandemic plan and the associated procedures.
- Manage and co-ordinate the review of dossiers for pandemic influenza vaccines, which are the responsibility of the EMEA.
- Manage and co-ordinate the post-authorisation follow-up of centrally authorised antivirals used during the pandemic.
- Provide to CHMP, the Commission and the Competent Authorities of the Member States the outcome of the review of dossiers of pandemic influenza vaccines and the outcome of any opinion related to antivirals and vaccines.
- Convey a clear message on the status of the review of these dossiers at defined timepoint to all interested parties in the regulatory field, including the European Commission, the ECDC and Member States and communicate to health professionals and public at defined timepoints within the evaluation procedure.
- All of these activities should be undertaken in line with this plan and associated work instructions and SOPs (see Annex I).

III.B. Integration of the various EMEA activities to deal with the crisis

- Announcement of an influenza pandemic will trigger further EMEA activities, and most notably related to business continuity.
- The EMEA Gold crisis team (see below) will ensure that business continuity decisions elicited by the influenza pandemic (including, but not limited to, staff presence in the office, the holding (or not) of Committee and Working Party meetings) can be taken in a timely manner.

IV. CRISIS MANAGEMENT STRUCTURES

In order to deal successfully with a crisis, the following Crisis Teams and Task Force have been created:

- EMEA Crisis Teams – EMEA Secretariat
- EMEA Task Force – (Co-)Rapporteurs, BWP/VWP experts, CHMP and VWP chairpersons, EDQM/OMCL representative(s), EC representative(s), EMEA staff. The EMEA Task force is involved in the evaluation of pandemic influenza vaccines submitted via the centralised procedures.

For logistical reasons, and rapid and efficient management, the core members of the different teams will be supplemented by a wider operational team to handle the various activities required to support the review of dossiers and communication of outcomes to all of the interested parties. Because of the nature of a pandemic there needs to be a wider pool of staff members (backups) to support the EMEA crisis teams and task force.

In preparation for such a crisis, a Joint EMEA Industry Task force is also established (as defined in the guideline² and in the work instructions). This task force, which is dealing with pandemic influenza vaccines (only), has an advisory role during the interpandemic and pandemic alert period but not during the actual pandemic period. Therefore, it is not considered further in this crisis management plan.

IV.A. The EMEA Crisis Teams

1. Composition

In order to react promptly, in case of an influenza pandemic, the following EMEA crisis teams are established:

- a. Gold crisis team
- b. Pandemic Silver crisis team
- c. Pandemic Bronze crisis team

The **Gold crisis team** is composed of the Executive Director of the EMEA and the Heads of Units, and has already been set up in the EMEA in the framework of Business Continuity Planning (BCP)³. This Gold crisis team is assisted by appointed EMEA staff providing technical support and scientific input, according to the topic, which in this case is specifically pandemic influenza.

The Pandemic **Silver crisis team** is composed of the Heads of Operational and Support Sectors; the responsibilities of the sectors include:

- Review of dossiers – Quality, Safety and Efficacy
- Post-authorisation activities – Quality, Safety and Efficacy and Pharmacovigilance
- Inspections
- Executive support
- Information Technology
- Meetings, Management and Conference Services
- Infrastructure Services
- Regulatory Affairs and Organisational Support
- Legal Affairs

The Pandemic **Bronze crisis team** is composed of appointed EMEA Scientific Administrators and Secretaries, and their back-ups, trained on, and dedicated to, pandemic activities. It also incorporates the Pandemic Intelligence Team.

2. Roles of the different EMEA Crisis teams

The different crisis teams are established by decision of the Executive Director at the latest during the pandemic alert period (Phase 4) and should become operational within the shortest possible timeframe after the announcement of the pandemic. They will be set up in such a way that they are able to deal with crises arising after office hours, during weekends and public holidays as well as during normal office hours.

² Guideline on submission of marketing authorisation applications for pandemic influenza vaccines through the centralised procedure (EMEA/CPMP/VEG/4986/03 of 5 April 2004).

³ For the exact composition of the Gold Team, please consult the SOP on BCP. EMEA/397403/2005 0.1, CURRENT

The EMEA *Pandemic Intelligence Team*⁴ 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 for an increase in pandemic alert level, or an imminent announcement of an influenza pandemic, will be cross-checked, promptly, with dedicated contacts at Commission (DG Sanco) and/or at WHO or WHO collaboration laboratories. Confirmed signals will (via Head of Sector Quality) be brought to the attention of the EMEA Gold Crisis Team.

The decision to convene the EMEA Gold Crisis Team will be taken by the Executive Director on the basis of information coming from the EMEA Pandemic Intelligence Team and/or from DG Sanco/WHO.

The primary role of the EMEA **Gold Crisis Team** is:

- To confirm the onset of the Influenza pandemic;
- To initiate the crisis plan and procedure for the fast-track approval of pandemic influenza vaccines as described in process map and associated work instructions (Annex 1) and inform CHMP. A formal announcement of the pandemic by WHO/DG Sanco is required to initiate the EMEA pandemic influenza crisis activities;
- To initiate the EMEA Communication policy;
- To initiate the EMEA business continuity plan and to evaluate future BCP actions.

The meeting of the EMEA Gold Crisis Team is normally chaired by the Executive Director, or, in his absence, a designated deputy. In addition and depending upon the circumstances, meetings may be held in part, or completely, by telephone or video-conference.

The primary role of the EMEA Pandemic **Silver Crisis Team** is:

- To mobilise the Bronze Team and inform them of the decisions of the Gold Team. To assign staff (with back-ups) from relevant sectors that will be dedicated to pandemic activities, as required;
- To direct and manage the crisis plan and procedure for the fast-track approval of pandemic influenza vaccines as described in process map and associated work instructions (Annex 1);
- To keep CHMP informed;
- To ensure that the communication policy and strategy is implemented.

The Pandemic **Bronze Crisis team** will run, in conjunction with EMEA Task Force/CHMP, the procedures related to the approval of pandemic influenza vaccines as described in process map and associated work instructions (Annex 1).

The detailed tasks of the Gold, Silver and Bronze crisis teams and the tasks of the different members of these teams are included in the relevant work instructions.

IV.B. EMEA Task Force

1. Composition

- (Co)-Rapporteurs of the core pandemic dossiers;
- (Co)-Rapporteurs appointed for pandemic vaccines for which a core dossier has not (yet) been submitted;
- Scientific assessment team supporting the (Co)-Rapporteurs;
- VWP / BWP experts;
- Chairperson of CHMP, BWP, VWP and PhVWP;
- EDQM/OMCL representative(s);
- EC representatives (DG Enterprise and DG Sanco);

⁴ A detailed Work Instruction / SOP describing the establishment, role and working of the EMEA Intelligence Team will be developed.
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- EMEA staff.

This task force can be supplemented with additional experts and representatives, such as members of the Inspectorate Working Party and/or GMP inspectors from the supervisory authorities and representatives from WHO.

2. Role

The EMEA Task Force is established specifically to deal with pre- and post authorisation activities related to pandemic influenza vaccines, and is established at the latest during the Pandemic Alert Period (Phase 4).

The task force will meet after the announcement of the influenza pandemic (Phase 6) and before the submission of the Pandemic variation (in case a core dossier has been approved) or an application for a conditional marketing authorisation (in case no core dossier has been approved) as described in the Work instructions.

The role of this team is to:

- Evaluation of data packages submitted by the Marketing authorisation holder or applicant prior to the submission of the pandemic dossier (pandemic variation or conditional marketing authorisation application). Prepare reports for approval by CHMP;
- Interact with the manufacturers, including ongoing scientific discussions prior to the submission of the pandemic dossier;
- Provide information and advice to EMEA
- Provide information and advice, via the CHMP, to Regulatory Authorities (MRFG, National Authorities, Commission services);
- Discuss and evaluate post-authorisation data, as necessary.

The EMEA will provide support to the activities of the EMEA Task Force as described in the work instructions.

IV.C. EMEA management: specific roles and responsibilities during the pandemic

- Executive Director of the EMEA, as well as the members of the EMEA Gold Crisis Team:
 - Chair the EMEA Gold Team;
 - When a high-level response is required:
 - Act as a public spokesperson⁵;
 - Liaise with external parties (such as European Commission, Member States etc) concerned by the crisis;
 - Plan the public relations policy and ensure that at all times an appropriate public statement is available;
 - Provide all necessary scientific resources.
- Heads of Operational and Support Sectors, including;
 - ***Review of dossiers for pandemic influenza vaccines – Quality, Safety and Efficacy***
Responsibilities of the Head of Quality Sector are to:
 - Co-ordinate and progress the review of all dossiers submitted to the Agency, in liaison with the Head of Safety and Efficacy Sector;
 - Report to the EMEA Gold team and CHMP on the outcome of these reviews on an on-going basis, until the reviews are completed;
 - Organise and co-ordinate the actions of the EMEA Task Force and Evaluation Project Team⁶

⁵ For routine, day-to-day communications, this task will be performed by the Executive Support sector.
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- Interact with manufacturers and/or marketing authorisation holders or applicants of pandemic influenza vaccines and antivirals;
 - Ensure that documents for CHMP are prepared in a timely manner;
 - Inform the Executive Director, the EMEA Gold Team and the Head of the Human Units of all developments;
 - Ensure that supportive technical documents for external communication are prepared and routed through the Press Officer.
- ***Post-authorisation activities – Safety and Efficacy and Pharmacovigilance***
Responsibilities of Head of Pharmacovigilance and post-authorisation Safety and Efficacy Sector are to:
- Co-ordinate the post-authorisation and pharmacovigilance activities related to centrally authorised antivirals and pandemic influenza vaccines;
 - Alert the CHMP and gold crisis team on safety signals arising from the use, during the pandemic, of non-centrally authorised antivirals or the bulk active substance (of centrally authorised antivirals), identifying the need for CHMP actions in accordance with art 5 and art 57 of Regulation (EC) No 726/2004;
 - Ensure that documents for CHMP are prepared in a timely manner;
 - Inform the Executive Director, EMEA Gold Team and the Head of the Human Unit of all developments;
 - Ensure that supportive technical documents for external communication are prepared and routed through the Press Officer.
- ***Inspections***
Responsibilities of Head of Inspection Sector are to:
- Ensure the assessment of current status of manufacturing sites involved in the manufacture of pandemic influenza vaccines or antivirals, identification of need for specific inspection or additional GMP information;
 - Coordinate any other inspection related activities.
- ***Telecommunications/IT***
Responsibilities of Head of Information Technology Sector are to:
- Assist the Human Units as detailed in the work instructions and SOPs, and more specifically in relationship to:
 - Computer facilities and remote assess
 - Tele and video communication
 - Emergency web update;
 - Coordinate any other IT related activities related to pre- and post-authorisation activities for pandemic influenza vaccines and antivirals.
- ***Meeting Management***
Responsibilities of the Head of Meeting Management and Conference Sector are to:
- Assist the Human Units as detailed in the work instructions and SOPs in relationship to the organisation of meetings (travel and hotel bookings for experts, booking of meeting rooms, etc.) during the influenza pandemic.
- ***Executive Support***
Responsibilities of the Head of Executive Support Sector are to:
- Co-ordinate the communication activities based on the policy of the Agency;
 - Ensure the coordination of the Agency's communication activities with the activities of our European partners (i.e. European Commission / DG Sanco, ECDC, national competent authorities);

⁶ Evaluation project team, as defined in the Guideline on submission of marketing authorisation applications for pandemic influenza vaccines through the centralised procedure (EMEA/CPMP/VEG/4986/03 of 5 April 2004) and associated work instructions, is set up specifically to perform the fast-track evaluation of the Pandemic vaccine type II variation.

- Co-ordinate the preparation and finalisation of information documents, such as press releases, question and answer documents, etc.;
- Ensure, in collaboration with the Personnel Sector, internal communication for staff related (BCP) issues;
- Ensure, in collaboration with the staff responsible for Web Services, timely update of the website;
- Respond to press enquiries.

V. EMEA COMMUNICATIONS POLICY AND STRATEGY

Effective communications will be crucial in the event of an influenza pandemic. This will require timely and effective co-ordinated responses from each of the Agency's European partners, namely the European Commission, ECDC and the EU Member States, healthcare providers, the media and the public in general. Therefore, the EMEA Pandemic Influenza Crisis Management Plan includes details of the EMEA communications strategy focussed on this crisis. This strategy, and its implementation steps, take into account the role and responsibilities of the EMEA in relationship to the other European partners cited above.

The EMEA has specific responsibilities in relationship to medicinal products. In this context, the Agency should be pro-active and prepare, in advance, texts required according to the policy of the Agency and the strategy to implement that policy. This will involve informing all interested parties, without encroaching on the activities and responsibilities of other European and national partners.

The Agency's communications approach will be tailored to fit in with those of the European Commission, the ECDC and the Member States. The overall aim is to ensure coordinated and consistent communications, which present coherent messages at the level of the European Union.

SOPs / work-instructions will address how the policy and strategy should be implemented.

The EMEA will issue public statements as described in the work instructions, so that interested parties are kept informed about the progress of the evaluation of dossiers, in an appropriate manner.

In order to apply the EMEA policy and strategy the Executive Support and the Press Office will be the single route through which all communications are channelled.