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on Pandemic Influenza Preparedness and Response Planning in the European Community
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1. **BACKGROUND AND AIM OF THE COMMUNICATION**

Many European citizens are affected by influenza every winter. In a normal seasonal influenza epidemic, between 5 and 10% of the population becomes ill. Past influenza pandemics have affected the population with much severe magnitude than seasonal epidemics, with attack rates ranging from 10 to 50%. There were three pandemics in the twentieth century: the Spanish flu of 1918-1920 (the largest; it caused more than 20 million deaths, perhaps even 50 million deaths worldwide), the Asian flu of 1957-1958, and the Hong Kong flu of 1968-1969. The progression of a highly pathogenic avian influenza (HPAI) epidemic from China and Southeast Asia has given rise to concerns that an influenza virus might arise, fully adapted to human-to-human transmission and capable of causing millions of deaths and huge economic damage.

Whilst it is impossible to predict next pandemic’s onset, health, social and other essential services are likely to be under severe pressure from its outset. An influenza pandemic would result in a high level of public, political and media concern and will cause, throughout and beyond the pandemic period, widespread social and economic disruption. Anxiety, movement restrictions, constraints on public gatherings, distribution difficulties, great number of excess deaths are all likely to add to pressures and disruption to the society.

Effects of the pandemic on societies are inevitable, but careful preparedness and response planning can contribute to mitigating the extent and impact. Comprehensive national and local communications strategies that are complementary and supported by mechanisms to ensure timely, accurate and clear advice and information must be fundamental to all plans. Planning for a pandemic is a complex matter as there is little knowledge of the likely impact: data are uncertain and lack common features. Based on previous pandemics, expert advice and theoretical modelling, most national preparedness plans are based on planning assumptions which include:

**Attack rate**: this is the proportion of the population that develop clinical influenza during a pandemic. In the absence of any intervention, planners assume that over a period of 9 to 15 weeks some 30% of the population will become ill. Attack rates, and severity of illness, are likely to vary between age groups, but as neither children nor adults are likely to have immunity to the new virus, for planning purposes a uniform attack rate, more serious illness and higher mortality rates than normal ‘seasonal’ influenza must be assumed across all age groups.

**Case fatality rate**: the proportion of ill people that would die due to influenza. Most national plans base their assumptions on a percentage of 0.37% overall case fatality rate over a pandemic period.

**Clinical consultations**: 50% of the ill people are expected to seek general practitioner or outpatient medical care.

**Hospital admissions**: for acute respiratory and related conditions, influenza-like cases are likely to represent 1% of clinical cases.

**Rate of Intensive Care**: it is expected that 15% of the patients hospitalised for influenza-like illness will need intensive care, and 50% of these may need mechanical ventilators.
Work absenteeism: for planning purposes it should be assumed that a cumulative total of 30% of the work force will take five to eight working days off over a three-month period. Influenza spread will be accelerated in schools and other closed communities leading to a potential need to close schools. This, combined with travel disruption and the need for workers to provide care for family members and others, will exacerbate absenteeism.

It is primarily the responsibility of each Member State to take the measures best adapted to fight human influenza pandemics. However, no country can alone face the consequences of a pandemic. International cooperation is an absolute necessity if its impact is to be reduced. In the EU, where there are no internal borders, additional coordination measures are necessary. Hence the need for EU-level action.

All Member States have drawn up and strengthened their pandemic influenza preparedness in recent months with assistance from the Commission and the WHO, and further work is being carried out, backed by conclusions of the Council\(^1\) and of the Health Ministers at their informal meeting on 20 October 2005. the Commission takes on an important role in assisting Member States and coordinating measures at EU level, using in particular the Community Network for the epidemiological surveillance and control of communicable diseases\(^2\) and its Early Warning and Response System (EWRS)\(^3\) and their mandatory arrangements for official notification of disease cases and events and information, consultation and coordination of measures taken or planned. The Commission has worked for a number of years to help improve the pandemic preparedness of the European Union and its Member States, as described in the Commission working paper\(^4\) on the subject published in March 2004. Since then, the WHO has reviewed its description of the various pandemic phases (See ANNEX 1) and the European Centre for Disease Prevention and Control (ECDC) set up by Regulation (EC) No 851/2004 of the European Parliament and of the Council\(^5\) became operational in Stockholm in May 2005, providing advice and expertise and assisting the Commission by operating the EWRS. In view of these developments, it became necessary to revise the EU pandemic influenza preparedness and response plan. The revised plan is set out in this communication.

2. Pandemic Influenza Preparedness in the European Union

Recommendations on actions before and during pandemics have been issued by the WHO\(^6\) and serve as the basis for planning by countries all over the world. Planning at the EU level is based on the same recommendations, however, specific provision has to be made for certain circumstances and conditions particular to the EU. If pandemic influenza circumstances were identified first outside the EU, the recognition of the pandemic (Phase 6 of the WHO recommendations) will almost certainly be first issued by the WHO. However, recognition of a state of a public health emergency linked to the emergence of a pandemic strain may come earlier. Once the EU becomes affected, different Member States may move through the phases at different times and rates. Therefore, for EU purposes, the epidemic activity within the EU and in Member States has special significance and needs additional detail in the

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1. SAN 104, 9882/04, 2.6.2004
2. OJ L 268/1-7, 3.10.1998
5. OJ L 142/1-11, 30.4.2004
framework of the WHO classification. A series of measures to be considered at EU level are described in this communication for each phase and would apply in the specific epidemiological context.

In March 2005, the Commission and the WHO Regional Office for Europe organised a workshop to discuss pandemic plans and identify gaps and improvements needed. Political commitment, increased resources for pandemic preparedness, more research and the resolution of complex legal and ethical issues were identified as key issues and strong interest was expressed in developing common solutions and cross-border co-operation.

In July 2005, the Commission wrote to all Health Ministers, asking them to provide information about the state of preparedness of their country, in particular availability of national plans, anti-virals and vaccination policy. All responses and national plans were assessed by the Commission, in consultation with the Health Security Committee (ref.1) and the ECDC. They were further discussed between Health Ministers and the Commission at an informal meeting organised by the UK Presidency on 20 October and considered at a second EC/WHO joint workshop on 24 - 26 October 2005. Moreover, joint assessment visits with the WHO and ECDC have started to take place in EU Member States and other European Countries. The preliminary findings show that the state of preparedness is generally limited to the health sector. Some plans need to be made more operational – in particular contingency plans for health care facilities and civil services, as well as training for the workforce.

Most Member States have addressed in their plans priority issues such as command chain structure, communication strategy and laboratory capacity. About half of the Member States have so far covered measures on international travel, contact tracing and quarantine and limitation of movements. Some Member States have assessed the need for measures concerning national citizens abroad.

The Commission has conducted a simulation exercise on pandemic influenza (“Common Ground”) to test communications and preparedness plans and coordination between the Member States, Commission and Community agencies, such as the ECDC and the European Medicines Evaluation Agency (EMEA), as well as with the WHO. The results and lessons from this exercise will be important in the efforts to improve plans and their interoperability.

To ensure better cooperation between the public health and the animal health sectors the Commission brought together the Chief Medical Officers (CMO) and the Chief Veterinarian Officers (CVO) of the EU on 22 September 2005. This meeting marked the start of an ongoing process to ensure better coordination between veterinary and health authorities and services in addressing key aspects of influenza control.

Such is the nature of the threat that it is obvious that providing protection for Member States implies increasing protective and preventative measures globally. The Commission together with the Member States is also providing support to international collaborations, in particular the work of the UN Agencies such as the WHO, FAO, OIE, and the work of the World Bank, to assist third countries, especially countries which are currently affected by avian influenza, in order to improve their surveillance and disease control capacities, particularly the least developed and the most vulnerable countries, specifically referring to Africa and Asia. This will include assistance to provide access to essential medical products.

The EU proposes to co-sponsor a pledging conference with the World Bank and China to secure support for a form of Trust Fund to combat Avian Influenza worldwide.

It is also important that the Commission and Member States insist that epidemiological reporting be prompt, accurate and totally transparent across the world. There is also a need for the Community to facilitate increasing involvement of European Neighbourhood Policy (ENP) partners in work in this area. Currently Action Plans with six countries refer to such work (Ukraine, Moldova, Israel, Jordan, Morocco, Tunisia).

Concerning the most potent interventions to face up to a pandemic, the Commission and the Member States are working together to ensure availability of vaccines and anti-virals. The Commission, with help from the EMEA and the Member States, has published a document on a private-public partnership to encourage the production of pandemic vaccines in the shortest possible time. Key issues identified are coverage of as many virus sub-types as possible, clinical trials, increase in capacity by increasing inter-pandemic vaccination and surveillance of immunisation status and adverse effects. As regards anti-virals, the Commission has undertaken efforts to stimulate strategies for their acquisition and use and this has led to benefits for Member States in terms of insights and crucial information about conditions of supply and limitations, as well as interest in the pharmaceutical industry for involvement of more companies in this area.

Member States are also assessing, with the assistance of the Commission and the ECDC, the need and specifications for masks and other devices such as respirators.

3. Main Tasks for Member States, Commission and Community Agencies

A crucial element of responses to a pandemic at any level is to ensure that they are multi-sectoral and encompass services outside the health sector. Member States and the Commission must, therefore, have in place and update strategies for planning and coordination that will facilitate multi-sectoral collaboration.

The development of plans for pandemic influenza involves the principles and components of a planning process presented in the Commission Communication on strengthening coordination on generic preparedness planning for public health emergencies at EU level. Application of this planning process to pandemic influenza has identified the following key topics on which to base the EU pandemic influenza plan:

- planning and coordination
- monitoring and assessment
- prevention and containment
- health system response
- communication

These topics are dealt with in turn below.

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3.1. Planning and Coordination

The tasks required in each phase and at each alert level should be directed towards identifying and addressing the current impact and subsequent threat potential of the influenza outbreak in order to limit its consequences. Transition between stages of alert and action, however, need to be rapid, depending on the evolution of events, and certain phases or levels may have to be leapfrogged. Plans, therefore, need to be flexible to allow for this contingency.

EU added value can be achieved by improving coordination and communication among the Commission and the Member States with assistance from the ECDC, other European agencies such as the EMEA and the European Food Safety Agency (EFSA), and with the WHO. A three-tiered structure is foreseen:

First the Public Health Preparedness and Response Planning Group (PRPG) of the Health Security Committee as set out in the working paper of the Commission of March 2004, has to undertake a number of tasks such as exchanging information, communicating and reviewing existing national preparedness and response plans and providing advice on gaps and coordination needs between national plans, sharing expertise and good practice with other groups working on preparedness plans, and setting up groups to advise on particular aspects of contingency planning.

Secondly, all notification, exchange of information between public health authorities and consultation and coordination on measures, planned or taken by Member States must be done through the Early Warning and Response System of the Community, as set out in Decision 2119/98/EC\(^{10}\) establishing a Community Network for the epidemiological surveillance and control of communicable diseases and Decision 2000/57/EC\(^{11}\) on the Early Warning and Response System.

Thirdly, deployment of Outbreak Assistance Teams (OATs) will be part of the response mechanism. In collaboration with the Member States, the Commission has drawn up a core list of experts that could be dispatched and the ECDC is now taking this work forward. The teams would work with an agreed mandate, organisation, structure, and detachment procedures. The full range of tasks of the teams may vary according to the terms of reference to be defined by the ECDC, but would include the participation in outbreak investigation inside and outside the Community ensuring coherence and synergies with the EU’s external response in co-operation with the WHO and the provision of assistance in risk assessment and co-ordination of activities on site, in particular where they cross over Member State boundaries.

3.2. Monitoring and assessment

The most important task of the surveillance and diagnostic systems of the Member States is to provide early detection and characterisation of pandemic strains from clinical or other specimens and a reliable risk assessment as to its potential to cause widespread outbreaks in humans. Key elements are good coverage of virological diagnosis for suspicious cases, with rapid and effective characterisation of virus strains isolated from patients, and assessment of the epidemiological impact, in particular the burden of disease. Effective surveillance of influenza is a major part of ensuring a timely alert on an upcoming pandemic.

\(^{10}\) OJ L 268/1-7, 3.10.1998
The ECDC plays a co-ordinating role in the surveillance effort. The Member States are obliged to report influenza outbreaks to the Community network of communicable diseases set up by Decision 2119/98/EC. Being part of this network, the Early Warning and Response System (EWRS) is the central plank for the Community response. The system is interlinking the Member States’ public health authorities. Under EWRS, formal and prompt notification of cases must take place with immediate transmission of information by the Commission to all the Member States, as well as (prior, where possible) consultation and coordination of counter-measures by the Member States.

Surveillance of influenza infections in animals, in particular in bird populations, is important and is a requirement under EC law, as animals may harbour a great variety of influenza virus strains. Based on the experience gained from a EU-wide survey on domestic poultry and wild birds, a targeted surveillance programme will be further improved.

Timely communication of surveillance findings in humans and animals is essential in order to have the maximum time span to prepare for vaccine production and other public health counter-measures. Adequate laboratory capacity and enhanced diagnostic capabilities need to be in place to ensure effective surveillance and prompt identification of strains of influenza virus. Cooperation among laboratories in this respect is organised through the European Influenza Surveillance Scheme (EISS), a project aimed at monitoring influenza activity in all EU Member States through the networking of clinicians and laboratories, and assisting the Commission in influenza pandemic preparedness planning. EISS is co-funded by the Community in the framework of the Public Health Programme 2003-2008. However, national reference laboratories should be designated by all Member State competent authorities, and be recognised, where appropriate, by the WHO Global Influenza Programme as National Influenza Centres. The EISS laboratory network is currently taking the function of a “Community Reference Laboratory for Human Influenza” structure which is foreseen to be set up with support through the Programme of Community action in the field of Health and Consumer protection 2007-2013\(^\text{12}\) that the Commission proposed on 6 April 2005.

Sentinel clinical surveillance should start in Member States with good systems of case recognition by clinicians linked to virological surveillance and should include age-specific morbidity and where possible also mortality and rates of hospitalisation. Clinical manifestations may change, especially during the later pandemic waves when new patterns may emerge.

The impact of vaccination programmes and other health measures should be assessed as the seasonal patterns of circulating influenza strains and consequently the composition of vaccines vary from year to year. Greater emphasis should be placed on systematic surveillance of the impact of vaccination programmes on morbidity and mortality and on good information on the immunization status in the EU. Since pandemic vaccines will be produced only after some months following isolation of the pandemic strain but will be administered without the conventional trials, there will be a need for monitoring of its effectiveness, safety and side effects.

The ECDC assumes the tasks related to the epidemiological surveillance under the plan, takes part in the organisation and conduct of influenza outbreak assistance, and provides advice on

options and guidelines for appropriate responses in the various phases and levels contained in the plan.

The Commission is presently funding projects under the Public Health Action Programme (2003-2008) to strengthen surveillance and preparedness at EU level (see ANNEX 2).

3.3. Prevention and containment

A key countermeasure for preventing influenza is vaccination. A pandemic vaccine will be produced after the pandemic strain is isolated, but this may take some 6-8 months before it becomes available. Moreover, capacity for producing vaccines is inadequate. Each Member State should prepare plans for vaccinating priority groups. The Commission, with assistance from the ECDC and WHO already facilitates co-ordination of plans to ensure inter-operability and to avoid confusion and public concern over differences in the levels of health protection afforded in various parts of the EU.

At the onset of a pandemic, anti-virals constitute the first pillar of medical prevention and intervention until vaccines become available. Member States should consider how to use limited stocks due to limited current availability, and to prioritize those who should receive the drugs during the first wave, particularly focussing on those who are ill with the pandemic strain and, therefore, most likely benefit from early treatment. The Commission facilitates the exchange of information and sharing of good practice in this area. For both vaccines and anti-virals, issues of equitable distribution and “mutualisation” of stocks to fight the disease at source have been put forward, in view of the lack of manufacturing capacity in many countries and the perceived imbalance between rich and powerful countries that collect strains through collaboration programmes with poor and affected ones but benefit from (their) manufacturers’ production only themselves.

Information concerning the annual use of vaccines in risk groups and the general public should be collected to provide a basis for estimates of eventual needs during a pandemic. Estimates of probable needs during a pandemic would help the annual vaccine supply process. As part of the plan the following could be pursued:

- Provision of estimates of the need for vaccines, anti-virals and antibiotics from Member States according to the likely scenarios for their use,
- Determination of priority groups for vaccination, when vaccine is in short supply;
- Establishment of options for public health measures to minimise morbidity and social disruption when there is rapid accumulation of cases of influenza;
- Collection of information from manufacturers about production capacities and plans for vaccines, antivirals and antibiotics.

The Commission is supporting projects in this area. Most importantly, the Commission agreed with the Member States a policy document on public-private partnership (PPP)\(^\text{13}\) between public bodies and the vaccine industry to deliver influenza vaccine to the European Union population in the shortest possible time in the event of influenza pandemic.

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The work undertaken under the Council’s mandate in this area has produced already results in providing useful insights for the Member States to negotiate with industry and has prompted the industry to start producing mock-up files and reviewing costs and prices, as well as stimulating more companies to be involved in the production of vaccines.

Industry’s stated contribution to the PPP is the development of the prototype influenza vaccines in accordance with the guidance produced by EMEA\(^{14}\) to prepare mock-up dossiers. Four companies have announced their intention to prepare such a dossier in the coming months. Industry will ensure the production of the pandemic vaccines, using all facilities available at the time of the pandemic.

The public sector would support industry starting with the development of a library of seed stocks for manufacturing of influenza vaccine. It could furthermore provide support for clinical trials for the mock-up vaccine and development of post marketing surveillance systems. It would assist the industry in the clinical trials and data gathering of alternative vaccine formulations, including varying doses of antigen and the use of adjuvants. The public sector would further undertake serological and animal challenge studies to provide scientific evidence for the likely protective efficacy of candidate vaccines against a particular circulating pandemic strain. The time saved in having a vaccine available for public use by these activities is potentially 2 to 3 months and possibly more.

Current vaccine production capacity is not deemed to be sufficient to meet the demands of the Community in the event of a pandemic. Manufacturers’ reserve capacity is not likely to be enough to support a sudden increase in demand. Part of the public contribution would be to increase the use of inter-pandemic influenza vaccine, thus contributing to increasing capacity, by ensuring that uptake is raised to the levels recommended by the World Health Assembly resolution 56.19\(^{15}\) which foresees coverage of 75% of the risk groups identified by the Member States. It is noted that inter-pandemic vaccine uptake in 2005 has been greatly increased and stocks have run out in many EU Member States.

Work on the implementation of the public-private partnership is on-going to reduce significantly the ‘time to market’. To reach this objective and to accelerate the evaluation of new specific pandemic vaccines, the Commission has agreed with the EMEA to waive fees for the registration of dossiers Member States’ efforts to acquire pandemic vaccines might be supported by the Community following the tabling by the Commission on 6 April 2005 a proposal for a regulation of the European Parliament and of the Council establishing the European Union Solidarity Fund\(^{16}\) to develop the solidarity strand of the Commission’s integrated approach, in order to ensure response to major disasters or public health emergencies, independent of their nature and origin. The Commission calls upon Council and European Parliament to conclude the work on the proposed EUSF regulation as soon as possible with a view to its earliest possible entry into force.

The geographical scope is limited to Member States and countries negotiating their accession to the EU. The thematic scope includes public health threats and acts of terrorism. The fund remains limited to "major" disasters defined as events resulting in total direct damage in excess of EUR 1 billion or 0.5% Gross Net Income (GNI) of the affected country

\(^{14}\) \(\text{EMEA/CPMP/4986/03} \& \ \text{EMEA/CPMP/4717/03, Réf.: } \text{http://www.emea.eu.int/indem/indexh1.htm}\)

\(^{15}\) \(\text{http://www.who.int/gb/ebwha/pdf_files/WHA56/ea56r19.pdf}\)

\(^{16}\) \(\text{COM (2005) 108 final, 6.4.2005 } \text{http://europa.eu.int/comm/regional_policy/funds/solidar/solid_en.htm}\)
respectively, or if the Commission in duly justified and exceptional circumstances, where the consequences are particularly serious but which cannot be assessed on the basis of physical damage alone, it declares a disaster situation as "major". This will be particularly important to help protect the EU in the case of pandemics, in particular in officially recognised influenza pandemics. Effective protection will require widespread and rapid use of anti-viral drugs and vaccines.

The EUSF could be used to help refinance the cost of these drugs. Mobilisation of the Fund, as under the current procedure, would be possible only upon request of an eligible State. Following the Commission's assessment and proposal to the budget authority of an amount of financial assistance to be granted, the latter adopts a corresponding supplementary budget. The Commission will then adopt a grant decision, which is followed by the conclusion of an implementation agreement, leading to the payment for the grant.

With the proposal for a regulation establishing the European Union Solidarity Fund the Commission suggests strengthening and widening the possibilities for responding to public health emergencies. This covers the immediate medical assistance and measures to protect the population against imminent health threats, including the cost of vaccines, drugs, medical products, equipment and infrastructure used during an emergency. The use of this fund, however, is linked to specific requirements and represents in its basic concept a refunding and thus response type instrument, with standard procedures that usually take some time. Therefore, the Commission had suggested an advance funding mechanism to allow for a limited funding with short reaction time.

Availability of vaccines or antivirals to populations most at risk may, in critical situations, be further limited by measures imposed by Member State authorities to provide maximum protection to their own population. Measures should, therefore, be considered with a view to ensuring equity of access. Further collaboration with the industry, the Member States and others is needed. Measures should not, however, include the promotion of any behaviour in breach of EU competition rules.

Non-pharmaceutical measures such as hand-washing and social distancing will play important roles in reducing the impact of pandemic influenza. The ECDC, working with the Commission and national and international bodies, will prepare evidence-based guidance on these topics for use by the Member States.

Finally, the Commission, through its Research Framework programs, is since 1998 co-financing projects in the field of human pandemic influenza. These efforts should be carried on through the 7th Framework program17 (ANNEX 3).

3.4. Health system response

To ensure effective and safe treatment of human cases of a novel influenza strain, it is important that hospitals have well established emergency plans to handle numerous cases and ensure continuity and resilience, clinical guidelines are ready, supplies are available and staff is aware of admission criteria. It is Member States responsibility and competence to ensure that citizen have access to best practice and it is a Community objective that inequities in this area are smoothed among countries and regions. Moreover, staff working in health care

17 COM (2005) 119 final, 6.4.2005
should be aware of and trained in infection control measures. Member States should ensure the development and implementation of clinical management guidelines for patients with suspected and confirmed pandemic strain influenza infection. Guidelines for infection control are important to clarify the routes of transmission and ways to interrupt transmission through hygienic measures. Infection control is an essential part of patient management, and helps prevent further spread to the public, and Member States need to consider their neighbours’ quality of services to be ready to respond to citizens seeking assistance over the national borders.

It is crucial that health services adapt to pandemic conditions so that basic care for those most in need is maintained. In order to ensure this, several emergency steps need to be developed to ensure a sensible personnel and volunteer corps management and to make optimal use of facilities and available pharmaceutical products. In general, activities in this area should be based upon a general health emergency preparedness plan. It will be important to coordinate clinical care and health services plans with bordering jurisdictions to avoid that patients migrate across borders in expectation of better health care.

With its Communication\(^{18}\) on the Community strategic guidelines for cohesion policy in support of growth and jobs (2007-2013), the Commission suggested to include the prevention of health risks and filling the gaps in health infrastructure as strategic parameters for the future cohesion policy. For those Member States planning to develop horizontal cohesion policy programmes on health and those regions that intend to integrate health related priorities in their operational programmes, the Commission recommends a thorough linking between them and the national preparedness plans. Special attention should be paid also to possibilities offered by the forthcoming cohesion policy instruments on territorial cooperation, in particular the cross-border cooperation.”

3.5. Communication

**Communication to the public**

A communications plan has to be prepared for each phase and level. The more serious the threat, the more important it will be to ensure efficient communication to the general public and to the media.

The perceived threat of a pandemic can give rise to considerable media interest. Making reliable information about the potential threat should be a key priority of Member States, the ECDC and the Commission. Giving out authoritative information at an early stage will prevent the creation of an “information void” that the media may fill with speculation and rumour. To ensure they are in a position to do this, the Member State authorities in liaison with the Commission and the ECDC, should develop a range of ready to use media briefing materials about influenza. A number of Member States have already done this, and have for example, given a certain amount of basic information about the disease and the systems in place to respond to major outbreaks.

During an influenza epidemic, information about both EU level and national actions to address the threat will need to be communicated to the media, and the public, in a timely and consistent manner. **The approach to communication** needs to be considered early on in the

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\(^{18}\) COM(2005)304 final, 5.7.2005
process of addressing a potential pandemic. Member States, the ECDC and the Commission should further develop communication plans and endeavour to co-ordinate accurate messages and statements to the media about the threat and the planned measures in order to avoid confusion and contradictory statements.

One way of ensuring the sharing of information among Member States and openness to the public and the media will be, during a pandemic, to publish regular reports on the Internet of the state of the pandemic around Europe. This way of working proved effective during the SARS outbreak.

Arrangements for vaccination and distribution of antiviral agents will vary from country to country depending on their national plans. Communicating to health professionals and to the public about these arrangements will necessarily be a task for Member State authorities. Nonetheless, even in these circumstances there will be a need for EU-wide co-ordination. It will help reinforce public confidence in the response strategy if Member States and the Commission can demonstrate that the national strategies across the EU are consistent and based on a common assessment of the relevant science.

Communication among competent health authorities

Fast exchange of information and prompt notification during the first stages of a pandemic influenza are essential in enabling Member States, the Commission, the ECDC, WHO and other bodies to respond with common positions in public communications, and alert properly their structures, so that measures can be implemented in a timely manner.

The Commission has undertaken action to coordinate the media services of the authorities of the Member States in charge of public Communications on pandemic influenza. In October 2005 a technical guidance document on ‘Procedure for Communication to Member States, the Commission and the ECDC about highly pathogenic Avian Influenza events in humans’ has been agreed and published on the Europa website19.

4. Pandemic Phases and EU Alert Levels

The key measures to be planned and implemented in regard to influenza pandemics can be grouped under the phases and levels presented below. Different sets of action have to be undertaken by the Commission and the Member States, but there are also actions that have to be carried out jointly. Actions are assembled for various phases and levels and would benefit from the assessment of the epidemiological situation carried out by ECDC and the WHO on the basis of scenarios and geographical spread as described below.

The choice of phases and levels is consistent with the recommendations of WHO and its definition of pandemic phases. However, due to the specific circumstances of the European Union, which is characterised by the absence of internal borders and the free circulation of persons and goods, the following four levels of EU alert are to be used under WHO Phase 6 (pandemic period), following consultation with Member States, WHO and ECDC:

**EU Alert levels in pandemic phase 6:**

**One** – no confirmed human cases infected with the pandemic virus in any EU Member State;

**Two** – one or more confirmed human cases infected with the pandemic virus in any EU Member State;

**Three** – a confirmed outbreak (transmission) with the pandemic virus in any EU Member State;

**Four** – widespread transmission in EU Member States

Within these alert levels and especially Alert Level 4, experience with seasonal influenza transmission suggests that pandemic activity will not be uniform across the EU and this will be the described by Member States and the ECDC. A planning assumption is that the pandemic does not emerge in a Member State and additional measures will need to be undertaken between the first and second waves of a pandemic and after a vaccine becomes available.

The following actions are common to each pandemic phase and therefore will be considered by the relevant actors each time the situation moves to a subsequent phase:

**Planning and coordination**

- Member States are obliged to inform, consult and coordinate measures with the other Member States and the Commission using the EWRS and, where appropriate, other mechanisms;

- Commission organises the information, consultation and coordination of measures.

**Monitoring and assessment**

- Member States are obliged to transmit information on detected human cases to the Network on communicable diseases, and the ECDC, using the Early Warning and Response System;

- Commission is coordinating the exchange of information with the assistance of the ECDC which is operating the EWRS.

**Prevention and containment**

**Public health interventions**

- Commission, with the assistance of the ECDC, to reiterate appropriate and inappropriate measures for affected and unaffected countries;

- Commission to advocate that appropriate international organizations and associations and transportation companies develop and prepare to implement standard measures for travellers on board international conveyances, consistent with the pandemic phase;
– From phase four through six: Commission, in consultation with the Member States, to assess needs for recommending additional containment measures, e.g. at international borders.

Communications

– Commission to work with Member States, with the assistance of ECDC and in cooperation with the WHO, to provide accurate messages relating to the pandemic phase;

– Commission regularly briefs media and the public on the situation, maintains capacity for meeting expected international information demands and evaluate and updates communications response during the various phases in the light of lessons learned.

**WHO PHASE 1 (Inter-pandemic period)**

In this phase no new influenza virus subtypes have been detected in humans.

An influenza virus subtype that has caused human infection may be present in animals. If present in animals, the risk of human infection or disease is considered to be low.

The main public health goal is strengthen influenza pandemic preparedness at the global, regional, national and sub-national levels.

This scenario includes no novel avian influenza virus detected in animals in Europe, and no human case.

**WHO PHASE 2 (Inter-pandemic period)**

No new influenza virus subtypes have been detected in humans.

However, a circulating animal influenza virus subtype poses a substantial risk of human disease.

Main public health objective is to minimize the risk of transmission to humans; detect and report such transmission rapidly if it occurs.

This scenario includes no human case in the EU.

**Responsibilities and actions**

In phase 1 and 2 strengthening influenza pandemic preparedness at national and international levels is of pivotal importance in preparing the response in the event of a pandemic. To update the status of preparedness at Community level, the Commission and the ECDC, in consultation with the Health Security Committee and in cooperation with the WHO, assess review and organise exercises concerning national pandemic plans, with a special focus on their interoperability.
WHO PHASE 3 (Pandemic alert period)

Human infection(s) with a new subtype, but no human to human spread, or at most, rare instances of spread to a close contact.

In this phase, the main public health objective is to ensure rapid characterization of the new virus subtype and early detection, notification and response to additional cases.

No human cases but risk of sporadic importation or appearance of isolated cases in Member States.

Responsibilities and actions

4.1.1. Commission

Planning and coordination

– Coordinate guidance to national authorities in reviewing and updating national contingency plans, based on evolving scientific information about the human case(s);

– Review Commission internal contingency plan.

Prevention and containment

Public health interventions

– Request affected Member States to inform the Commission and other Member States on implementation and effectiveness of containment measures with a view to their coordination, via the EWRS system;

Anti-virals

– Work with national authorities to coordinate availability so that they could be swiftly deployed;

Vaccines

– Work with national authorities to assess the possible benefits and disadvantages of vaccinating persons with occupational and other exposures with seasonal vaccines, and to plan vaccination programmes if appropriate;

– Work with the Member States and the industry to encourage the availability of effective and sufficient vaccines.

Health system response

– Encourage national authorities to review and update health system response strategies at national and sub-national levels.
Communications

– Coordinate sharing of background information regarding the effectiveness of recommended measures;

– Update other partners, stakeholders and the public on the global epidemiological situation and disease characteristics;

– Coordinate sharing of information regarding the effectiveness of recommended measures with the assistance of the ECDC.

4.1.2. ECDC

Monitoring and assessment

– Monitor the pandemic influenza threat through gathering information and collaboration with European Agencies (e.g. EFSA) and international bodies (WHO, OIE, FAO) and communicate regularly about its risk monitoring activities;

– Facilitate sharing of information of laboratory confirmation of the human infection through the network of reference laboratories;

– Co-ordinate development of a case-definition for reporting by countries;

– Provide report forms and co-ordinate rapid reporting of human infections with a new influenza virus strain by appropriate means;

– Provide appropriate support to national authorities in investigating case(s) and the epidemiological circumstances of infection, and in identifying risk groups;

Health Systems Response

– Provide scientific advice about non-pharmaceutical control measures in order to provide guidance to Member States in their Response Strategy

Communications

– Work with Member States to promote consistent messages on the disease and the epidemiological situation;

– Coordinate sharing of background information regarding the effectiveness of recommended measures in consultation with Commission

– Regularly update other partners, stakeholders and the public on the global epidemiological situation and disease characteristics.
4.1.3. Member States

Monitoring and assessment

– Ensure rapid reporting of laboratory confirmation of the human infection through the network of reference laboratories;

– Apply EU-agreed case-definitions for reporting;

– Ensure rapid reporting of human infections with a new influenza virus strain by using the EWRS and, where appropriate, other mechanisms;

– Investigate case(s) and the epidemiological circumstances of infection, and identify risk groups and promptly communicate the results to the Commission and the ECDC.

Health System Response

– Review, update and disseminate guidelines for clinical care, diagnostics, treatment, infection control and safe specimen handling.

Communications

– Work with other Member States and the Commission to provide accurate messages;

– Share with the other Member States and the Commission information regarding the effectiveness of recommended measures;

– Regularly update other partners, stakeholders and the public on the global epidemiological situation and disease characteristics.

WHO PHASE 4 (Pandemic alert period)

Small cluster(s) with limited human-to-human transmission but spread is highly localized, suggesting that the virus is not well adapted to humans.

Main public health goal is to contain the new virus within limited foci or delay spread to gain time to implement preparedness measures, including vaccine development.

There are no human cases in EU but a heightened risk of importation or appearance of isolated cases in Member States and increased risk of transmission from them.

Responsibilities and actions

4.1.4. Commission

Monitoring and assessment

– In consultation with the ECDC, coordinate strategies of national authorities to enhance surveillance in risk groups;
In consultation with the ECDC, coordinate with national authorities the monitoring of measures on containment and control.

Prevention and containment

Public health interventions

– Coordinate implementation of recommended additional containment measures.

Health system response

– Encourage national authorities to reassess guidelines for clinical management and infection control in health care (including long-term care facilities);

– Encourage national authorities to prepare for the next phase, including a mobilization plan for health-care workers.

Communications

– With the assistance of the ECDC, promote sharing of templates for general health education materials.

4.1.5. ECDC

Monitoring and assessment

– Monitor the risk for the EU with special emphasis on the potential for importation of cases from affected areas

– In consultation with the Commission, coordinate strategies of national authorities to enhance surveillance in risk groups;

– Facilitate reporting of human-to-human transmission of infection with a new influenza virus strain by national authorities using the EWRS;

– Provide appropriate support to national authorities in investigating cases and contacts, enhancing disease surveillance to identify additional cases, and the epidemiological circumstances of infection (e.g. source of exposure, infection of contacts, and spread in the general population), and in identifying risk groups;

Public health interventions

– Provide scientific advice on non-pharmaceutical public health interventions;

– In consultation with the Commission, request affected Member States to report on implementation of enhanced surveillance measures, assist in evaluating the effectiveness of such measures, and transmit appropriate
information to all Member States to inform national and international planning;

– Review guidelines for biosafety in the influenza laboratory network.

Communications

– Ensure regular updating of information regarding the risk for the European Union and the scientific appraisal of recommended measures.

4.1.6. Member States

Monitoring and assessment

– Share information on enhanced surveillance in risk groups and on the effectiveness of measures on containment and control.

Prevention and containment

Public health interventions

– Consult the other Member States and the Commission on any additional containment measures planned.

Health system response

– Share guidelines for clinical management and infection control in health care (including long-term care facilities);

– Report and consult on preparations for the next phase, especially as regards nationals of other Member States and plans for assisting other EU nationals in third countries, including protection in situ and repatriation.

Communications

– Share intended messages to the public and educational material with the other Member States, the Commission and the ECDC

WHO PHASE 5 (Pandemic alert period)

Larger cluster(s) but human-to-human spread still localized, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk).

In this phase there is a need to maximize efforts to contain or delay spread, to possibly avert a pandemic, and to gain time to implement pandemic response measures.

Localised large clusters in countries outside Europe with human-to-human transmission with no confirmation of international spread; there is a progressively rising risk of importation or appearance of isolated cases in EU.
Responsibilities and actions

4.1.7. Commission

Planning and coordination

– Coordinate the ongoing evaluation of interventions;

– Finalize preparations for imminent pandemic, including internal organization and staff surge capacity;

– Activate Commission contingency plan;

Prevention and containment

Public health interventions

– Collaborate with national authorities in assisting distribution of infection-control supplies to health-care settings providing care to human cases, especially if these supplies are from other Member States;

– Review Community measures or possibilities for proposals of measures in all relevant sectors of Community policy.

Anti-virals

– Collaborate with national authorities in targeting antiviral prophylaxis to the appropriate groups and persons and assist in coordination of mobilising other Member States’ stockpiles if that is necessary;

Vaccines

– Promote, with assistance from the ECDC, with national authorities preparation and implementation of targeted vaccine campaigns involving appropriate groups and persons in the affected community, if pandemic vaccine is available;

Health system response

– Coordinate, with the assistance of the ECDC, guidance to national authorities in assisting clinicians in recognition, diagnosis and reporting of cases;

– Coordinate, with the assistance of the ECDC, guidance to national authorities to optimize use of scarce facilities (triage, modified clinical guidelines, modified hospital infection guidelines, protection of non-influenza health care services, alternative care, etc.);
Communications

– Encourage application of recommended measures for the public despite their possible limitations, and about interventions that may be modified or implemented during a pandemic.

4.1.8. ECDC

Monitoring and assessment:

– Monitor the risk for the European Union with special emphasis on the potential for importation of cases from affected areas;

– Promote intensification of disease surveillance in countries not yet affected, to the maximum extent possible;

– Review and adjust case-definition and guidelines if needed;

– Accelerate and enhance situation monitoring and assessment activities started in pandemic phase 4, to a maximum;

– Promote monitoring of health-care needs and facilities in countries at risk;

– Promote mathematical modelling to forecast trends for the first pandemic wave (affected regions, risk groups, health-care resource needs, impact, etc.).

Communications

– Update partners and stakeholders, and the public on the global situation, trends, epidemiological characteristics and recommended measures as well as the situation and risk within the EU.

4.1.9. Member States

Monitoring and assessment

– Assess the risk and inform promptly on investigations

Prevention and containment

Public health interventions

– Coordinate with the other Member States and the Commission, additional containment measures.
Health system response

- Implement guidelines for clinical management and infection control in health care (including long-term care facilities);
- Share contingency measures for the next phase, especially as regards nationals of other Member States and plans for assisting other EU nationals in third countries, including protection in situ and repatriation.

Communications

Share intended messages to the public and educational material with the other Member States, the Commission and the ECDC

<table>
<thead>
<tr>
<th>WHO PHASE 6 (Pandemic period) – EU Alert levels –1 to 4</th>
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<tbody>
<tr>
<td>Pandemic: increased and sustained transmission in the general population.</td>
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<tr>
<td>Several outbreaks in at least one country outside EU with sustained human-to-human transmission, and spread to other countries.</td>
</tr>
<tr>
<td>Main public health objective is to minimise the impact of the pandemic.</td>
</tr>
</tbody>
</table>

The following scenarios for the EU may occur in WHO Phase 6 and differ in the epidemiological pattern and geographical spread, and occur in chronological order;

**EU Alert level 1**

- No human case in the EU. Very high risk of introduction or suspicion of sporadic imported cases into Europe;

**EU Alert level 2**

- Isolation of pandemic subtype from a single human case inside the EU;

**EU Alert level 3**

- Isolated cluster with a pandemic subtype in one EU Member State or sustained human-to-human transmission with multiple clusters confirmed inside the EU;

**EU Alert level 4**

- Widespread activity in one or more Member States.

**Responsibilities and actions**

Actions will be phased by alert level, and implemented in consultation with all concerned partners, following an assessment of the ECDC on the epidemiological situation and predictions of evolution, and evaluation of effectiveness of measures taken by Member States. As the situation evolves along the alert levels, actions need to be coordinated in particular between consecutive waves of the pandemic and in relation to the availability of a vaccine.
4.1.10. Commission

Planning and coordination

– Establish and activate pandemic influenza information and coordination centre;
– Interact with organisations and agencies to coordinate interventions at EU and international level and coordinate Member State positions;
– Coordinate ongoing development of guidelines;
– Coordinate evaluation of measures and assessment of their impact.

Prevention and containment

Public health interventions

– Coordinate with the Member States the position on movement of persons and goods and cooperate with appropriate international organizations and associations and transportation companies to implement standard measures for travellers on board international conveyances, consistent with the alert level;
– Coordinate with the Member States the assessment of the impact of measures, with the assistance of the ECDC, in particular on the use of anti-virals and the effect of targeted vaccination campaigns.

Health system response

– Facilitate mutual aid arrangements between Member States according to the phasing of the pandemic, including mobilization of immune healthcare workers and the transfer of medical assets.

4.1.11. ECDC

Monitoring and assessment

– Monitor the spread of disease, risk groups, case fatality rate and transmission rate, and coordinate adjustment of case definitions;
– Coordinate the clinical, microbiological and epidemiological characterisation of the pandemic strain in the first reported clusters in the EU in order to determine the transmission rate, case fatality ratio (attributable mortality) and affected age groups.
– Coordinate monitoring for possible changes in epidemiological, clinical and virological aspects of infection, including antiviral drug resistance;
– Coordinate national reporting of estimated national impact and assist global situation monitoring (global spread, national trends);
– Encourage preparation of forecasts for the next wave (new affected regions, risk groups, health care resources, etc.);

– Review lessons learnt and make adjustments in surveillance guidelines and tools for countries.

Prevention and containment

Public health interventions

– Coordinate and facilitate assessment of interventions and update recommendations if needed;

– Respond to requests for the deployment of outbreak assistance teams;

Anti-virals

– Update, in consultation with Member States and the Commission, guidance on the optimal use of available agents;

– Coordinate with Member States, the Commission and partners (notably, EMEA) monitoring of coverage, effectiveness, side effects and safety;

Vaccines

– When the pandemic vaccine becomes available coordinate with Member States, the Commission and partners (notably, EMEA) monitoring of coverage effectiveness, side effects and safety;

Communication

– Regularly brief international organizations, national authorities, other partners and stakeholders, and the public on the situation;

– Implement and maintain capacity for meeting expected international information demands;

– Evaluate communications response during previous phases; review lessons learned;

4.1.12. Member States

Health system response

– In consultation with other Member States and the Commission, promote improvement of guidelines and (updated) model algorithms for the triage of influenza and non-influenza cases;

– In consultation with other Member States and the Commission, promote development of guidelines on self-care.
4.2. **Post-pandemic period: recovery and return to inter-pandemic period**

After a pandemic wave is over, it can be expected that many people will remain affected in one way or another: many persons may have lost friends or relatives, will suffer from fatigue and psychological problems, or may have incurred financial losses due to interruption of business. Governments or other authorities have the natural role to ensure that concerns can be addressed and to support 'rebuilding the society'.

Member States should have a plan in place to ensure the quick revitalization of the country after a pandemic. This should include recovery plans for essential services, and identify agencies and individuals responsible to give social and psychological support to affected families and companies. A mechanism should also be in place to assess economic losses and to provide financial support to affected groups.

Member States should ensure that essential services develop recovery plans for their services or organisation. National preparedness plans should also consider whether recovery after a pandemic needs financial support from the government. If so, Member States should develop criteria for financial support and seek ways to ensure availability of funds.

The Commission, through the proposed Solidarity Fund, could help Member States in the effort of recovery and mitigation of economic losses due to the pandemic.

5. **CONCLUSIONS**

This Communication outlines the key elements and sets of actions of the Community Pandemic Influenza Preparedness and Response Plan. Implementation will require more detail to be developed for those charged with operational tasks in the Commission, the ECDC, the EMEA and the Member States’ authorities. It will need periodic revision in the light of international discussions and on the basis of experience, during seasonal influenza and from cross-countries exercises.

Close co-operation will continue under the auspices of the Commission between human and animal health authorities and experts at national and European level in the area of influenza virus infections. In this context, a mutual exchange of experiences in contingency planning is of major importance, as contingency plans in animal health are already well established and have proven to be effective in the past.

Preparing and responding to influenza pandemics presents a formidable challenge and requires increased efforts by the Member States and the Commission. This should be done as part of a more general approach to public health emergencies, in order to use scarce resources effectively, benefit from the widest possible expertise and keep procedures and functions manageable and as simple as possible; the Commission has published a communication on generic public health emergency planning to aid these efforts.

The European Centre for Disease Prevention and Control (ECDC) can provide a structured and systematic approach to the surveillance and control of influenza and other communicable diseases that might affect the people of the European Union. The ECDC can mobilise and significantly reinforce the synergies between the existing national centres for disease control and will no doubt help the Commission and the Member States to deal effectively with influenza.
Inter-sectoral action will be a key issue in tackling pandemic influenza. Many actions have already been undertaken at national and at EU level to ensure that measures in the various sectors of policy are effective and coordinated. But more needs to be done and the Commission and the Member States are carrying work forward in this respect. Particularly important will be the tackling of the pandemic problem at its source; the external action of the Community, in this respect, is important in helping the competent international organisations and third countries to face up to a possible pandemic and reduce its spread and impact.
ANNEX 1: New WHO Phases\(^{20}\)

<table>
<thead>
<tr>
<th>Pandemic phases</th>
<th>Public health goals</th>
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<tbody>
<tr>
<td><strong>Interpandemic period</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>No new influenza virus subtypes have been detected in humans. An influenza virus subtype that has caused human infection may be present in animals. If present in animals the risk of human infection or disease is considered to be low</td>
</tr>
<tr>
<td>2</td>
<td>No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease.</td>
</tr>
<tr>
<td><strong>Pandemic alert period</strong></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Human infection(s) with a new subtype, but no human to human spread, or at most rare instances of spread to a close contact.</td>
</tr>
<tr>
<td>4</td>
<td>Small cluster(s) with limited human to human transmission but spread is highly localized, suggesting that the virus is not well adapted to humans.</td>
</tr>
<tr>
<td>5</td>
<td>Large cluster(s) but human-to-human spread still localized, suggesting that the new virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk).</td>
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<tr>
<td><strong>Pandemic period</strong></td>
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<tr>
<td>6</td>
<td>Pandemic: increased and sustained transmission in general population</td>
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<tr>
<td><strong>Post-pandemic period</strong></td>
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<tr>
<td>Post-pandemic period: return to inter-pandemic period</td>
<td>Return to inter-pandemic period</td>
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ANNEX 2: Projects related to influenza funded under the public health programme

The European Commission, DG SANCO, is presently funding projects under the Public Health Action Programme (2003-2008), which are directly or indirectly related to influenza preparedness and response, as follows:

• EISS - The European Influenza Surveillance Scheme.

• MODELREL - EU co-ordination and dissemination of strategic modelling capabilities concerning the deliberate release of biological agents.

• EUNID - European Network of Infectious Diseases physicians.

• EPIET - European Programme for Intervention Epidemiology Training.

• Epi-North – A framework for communicable disease surveillance, communication and training in Northern Europe.

• INSIGHT - International network of national public health Institutes sharing information, expertise and capabilities in order to grapple with major health threats.

• VENICE - Vaccine European new integrated collaboration effort.

• EPIVAC - Europe-wide pandemic influenza vaccine coverage: good epidemic vaccination practice by establishing integrated national stakeholders networks.

• ETIDE - European Training for Infectious Disease Emergencies.

• Epi-South - Network for Communicable Disease Control in Southern Europe and Mediterranean Countries.

• FLUSECURE - Combating FLU in a combined action between industry and the public sector in order to SECURE adequate and fast interventions in Europe.

• VAC-SAT - Vaccine Safety - Attitudes, Training and Communication.
ANNEX 3: EU supported research related to human pandemic influenza


- FLUPAN - Preparing for an influenza pandemic
- NOVAFLU - Novel vaccination strategies and vaccine formulations for epidemic and pandemic influenza control

6th Framework Programme (2002-2006)

- VIRGIL - European vigilance network for the management of antiviral drug resistance
- SARS/FLU VACCINE
- FLUVACC - Live attenuated replication-defective influenza vaccine

7th Framework Programme (2007-2013)

On 21 September 2005 the European Commission proposed a Council decision concerning the Specific Programmes implementing the Seventh Framework Programme (2007-2013) of the European Community for research, technological development and demonstration activities including a proposal of a specific programme that has as heading ‘Cooperation’ and includes a particular section on health, which is consequently applicable to the field of flu.

The focus will be on confronting emerging pathogens with pandemic potential including zoonoses (e.g. SARS and highly pathogenic influenza). Where appropriate, provisions will be made for rapidly initiating collaborative research aimed at expediting development of new diagnostics, drugs and vaccines for efficient prevention, treatment, and control of infectious disease emergencies.