# Preliminary Conclusions and Recommendations

# as proposed by the audience

## Pandemic Preparedness in the Community:

## Influenza and other Health Threats

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## A. CONCLUSIONS AND IDENTIFIED NEEDS

The next pandemic is imminent. EU Member States are not prepared. Vaccine availability is not secured. Antiviral stocks do not exist and will not be under the current market forces. In the event of a pandemic millions of people could die, economies will be affected and services (medical, civil) could collapse. Members of the public will not excuse authorities, who will be held responsible for not having put in place up-to-date preparedness.

Therefore, a Community preparedness plan is needed which can be applied before a pandemic arises and immediately as it happens. All Member States have to complete and to implement national plans.

The Network on communicable diseases has to be strengthened. Areas to be improved are

- surveillance
- rapid response
- research
- coherence between veterinary and human surveillance

Better and more effective laboratories are needed, and there is a need to need to address the legal and social impacts of stockpiling of antiviral drugs and to secure access and availability of approved vaccines which is produced in just a few EU states.

Improving communication on the need for vaccination and the dangers of the disease are further requirements.

There is also a need for investigation teams.

International co-operation is also needed. Under the EU dimension a permanent platform for discussion needs to be in place to ensure commonality of approach. Scenarios and simulation exercises should be performed at Community level.

There is a need for a EU pandemic preparedness plan to complement existing national and regional plans which have to be actual.

## B. RECOMMENDATIONS

### 1. General recommendations

1.1. The Commission should consider the production of a standard operating procedure, which covers the responsibilities and actions to be undertaken by the relevant responsible authorities before and during each phase of the pandemic.

1.2. Several European countries have developed plans and a few, eg UK and France, are currently updating them. The national preparedness plans should be made public to all Member States.

1.3. Pandemic planning encompasses more than the domains covered by the Ministries of Health, and preparedness at a European level needs a political impetus to ensure that different government departments/agencies work together. Plans on paper are only a start. People need to be prepared. A manual of operations, simulation exercises and real time scenarios should be integral parts of preparedness planning.

1.4. Scenario analysis is helpful in making policy decisions and coping with pandemic planning because it provides insight into:

- the impact of the pandemic in terms of morbidity, deaths, and health care use;
- the impact of various interventions in terms of avoided influenza-related hospitalisations and deaths;
- crucial model parameters such as age, specific attack rates, hospitalisation rates and death rates;

The underlying decision support model

- can be used by other countries using country specific data.
- provides the opportunity to update estimates when there is an acute pandemic threat, based on surveillance data from the pandemic source region.

### 2. Surveillance

2.1. Ongoing virological and epidemiological surveillance should be improved to ensure adequate preparation for a pandemic.

2.1.1. European influenza experts should provide the European Influenza Surveillance Scheme EISS with comments.

2.1.2. Surveillance during a pandemic should be different from surveillance during the inter-pandemic phase. A surveillance system appropriate for a pandemic should be developed at EU level and rehearsed. Criteria should be developed to define how much surveillance is appropriate during the interpandemic and the pandemic phase

2.1.3. Surveillance should include data on vaccination and analysis of vaccine efficacy (age group specific etc).

2.1.4. Surveillance capabilities should be raised to evaluate the burden of disease in terms of severity (mortality, attack rates, hospitalization rates,

costs) to enable better alignment of control measures.Through improved evaluation of disease burden and of vaccine effectiveness, surveillance systems should enable the assessment of vaccine needs during the interpandemic phase to improve preparedness for increased vaccine demand during the pandemic period.

2.1.5. A protocol should be agreed for community wide studies of population susceptibility linked to models of epidemic spread empowered to provide recommendations for use of antivirals and vaccines.

Surveillance plans should also include plans for population based serological surveys to assess immunity to a new virus. These plans could help to inform on intervention strategies and could be activated as appropriate.

2.1.6. A system for quality control of laboratory methods should be established. Laboratories should seek accreditation for handling potential pandemic strains.

The laboratories involved in the Flu Surveillance in Europe (EISS) should be able to assess the characteristics of virus isolates. Original clinical specimens should be appropriately stored for subsequent isolation and characterization of virus.

The identification and characterization of new pandemic virus strains should be improved. Reference reagents for the characterization of all influenza viruses including new types should be made available.

The Member States and the Commission should agree on the designation and support of a Community Reference Laboratory in charge of manufacturing these reagents.

2.1.7. An appropriate infrastructure for animal influenza surveillance should be put in place. Human and veterinary surveillance systems should be linked to share information and reagents for strain identification.

2.2. The Commission should ensure continued funding of influenza surveillance in Europe.

2.3. Where national military surveillance programs exist, results should be integrated into EU influenza surveillance.

2.4. Surveillance data should be used

- to develop scenario's.
- to estimate the impact of morbidity and health care use.
- to compare interventions.

## 3. Vaccines

3.1. Vaccine production should be enhanced to minimize lack of appropriate vaccines during a pandemic, for example by increasing public awareness about a potentially deadly disease.

To ensure sufficient production and equitable distribution, the European Commission should

- Encourage the Member states to develop five-year forecasts for vaccine demand and communicate this information to all vaccine producers.
- Cooperate with political leaders of the Member States to develop politically acceptable alternatives to “national strategies” for vaccine production for all Member States.
- Production capacities, in particular the time frame needed for up-scaling vaccine production should be made known.

3.2. A mechanism should be put in place to ensure equitable access of European citizens to pandemic influenza vaccine and to avoid that countries will supply domestic markets first during a pandemic. The Commission should enter discussions with the WHO on equity issues for distribution of vaccines given a pandemic scenario.

3.3. The production capabilities of traditional inactivated egg produced vaccines should be evaluated.

3.4. Egg vaccine technology for pandemic vaccine production should not be discarded before alternatives are in routine use.

3.5. The potential of new vaccines for use during a pandemic should be fully exploited.

3.6. The suitability of cell-culture influenza vaccine technology as an important alternative to respond to the need of a pandemic vaccine should be exploited.

3.7. Research should be supported to establish adapted vaccination schedules (1 versus 2 shots, dosage) and to explore the benefits of adjuvanted and whole virus vaccines.

3.8. The implications of new vaccine production technologies on vaccine licensing and quality assessment should be analyzed.

The issue of intellectual property, affecting the use of new technologies for vaccine production during inter-pandemic periods should be resolved for pandemic vaccine production to avoid significant delays. Proposals should be made to resolve market authorization issues in the event of a pandemic, with a view to reducing the review time of 73 days.

For licensing of novel vaccines, companies should consider accelerated central authorization procedures to reduce regulatory hurdles and delays such as scientific advice from EMEA during RSD phase.

Current regulatory responsibilities for influenza vaccines in Europe should be reevaluated enforcing the role of the European Agency for the Evaluation of Medicinal Products (EMEA).

## 4. Antivirals

4.1. Production capabilities should be increased by raising public awareness about a potentially deadly disease.

4.2. Stockpiling should be established.

The Commission should develop consensus criteria to calculate the number of doses to be contained within the stockpile and a standard operating procedure to manage the stockpile during each phase of the pandemic.

4.3. The Commission should enter discussions with the WHO on equity issues for the distribution of antivirals given a pandemic scenario.