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NOTE

from : General Secretariat
to : Council

Subject : Pandemic Influenza Preparedness and Response Planning
– Written information by the Commission

Delegations will find attached a note from the Commission on the above subject.

PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE PLANNING
WRITTEN INFORMATION BY THE COMMISSION

INTRODUCTION

The Commission, in its working paper on Community pandemic influenza preparedness and response planning published on 20 March 2004 and the Council, in its conclusions of 2 June 2004, identified as key components of the EU strategy to face up to pandemic influenza the preparation and testing of national plans, surveillance and networking of national reference laboratories to identify the pandemic strain quickly, effective outbreak management through timely advice, early notification of cases, outbreak assistance and coordination of responses of Member States, and the adequate and timely supply of vaccines and anti-viral drugs. These are also key issues in the framework for cooperation on generic preparedness planning that the Commission has been developing following the Council conclusions of May 2003 on SARS. The Commission will table a communication later this year, based on the work accomplished in this area with the assistance of the Health Security Committee and which will take into account the new International Health Regulations, to set an agenda of sharing national plans and contributing to evaluations and improvements, identifying the contribution and role of Community legislation and arrangements so that national plans take them fully into account, and making appropriate arrangements and algorithms for sequences of events and actions to make coordination of responses possible.

In its conclusions of 2 June 2004 on influenza, the Council also called on the Commission and the Member States to facilitate technical assistance at an operational and a strategic level and work towards promoting co-ordination of national plans and conducting a joint evaluation exercise. Moreover, it requested the Health Ministers and the Commission to extend the mandate of the Health Security Committee to cover the area of Community pandemic influenza preparedness and response planning and review its mandate once the European Centre for Disease Prevention and Control has become operational.

PROGRESS WITH THE EU STRATEGY ON PANDEMIC INFLUENZA

- ***Co-ordination of national plans***

Together with the Regional Office for Europe of the World Health Organisation, the Commission organised a workshop on 2-3 March 2005 to facilitate the drawing up and/or improvement of national plans for the Member States of the EU and the European region of the WHO. Together with the WHO, a follow up is planned and a second workshop will be organised during the second semester of 2005. This will facilitate addressing the weaknesses identified and closing gaps. In addition, the Commission will support provision of advice to public health authorities with methods and review tools and will report back to the Member States on problems found.

- ***Joint evaluation exercise***

The Commission is organising a command-post exercise this autumn to test communications, exchanges of information and interaction between the competent authorities at EU level and the coordination and inter-operability of national plans. It will require the full support and direct involvement of Health Ministers and their enlisting of help from their colleagues in other government departments that are implicated in the management of major emergencies. A communication plan has been prepared and Health Ministers are requested to designate officials to liaise with the Commission in order to coordinate media handling. A conference is planned after the exercise to evaluate the lessons learnt and to prepare recommendations.

- ***Surveillance and laboratory networking***

The existing surveillance network established through Community co-funding (European Influenza Surveillance Scheme, EISS) provides a good basis for delivering on this crucial task but needs to be further developed and supported as should the network of laboratories for influenza in the Community. This is an area where the European Centre for Disease Prevention and Control (ECDC) is expected to assume the leading and determinant role. Meanwhile, the Commission will enhance collaboration between the Community network of laboratories for human influenza and the Community Reference Laboratory for Avian Influenza (animal health) starting with a joint workshop later this year which is expected to produce recommendations to be addressed to the Chief Medical Officers and the Chief Veterinary Officers.

- ***Outbreak assistance planning***

In order to facilitate the setting up a mechanism for outbreak assistance planning, the Commission has established a directory of experts on surveillance and control that will be shared with and managed by the ECDC for outbreak investigation inside and outside the Commission.

- ***Vaccines***

The Commission worked with the Health Security Committee and the European Vaccine Manufacturers to find an agreed way for ensuring sufficiency of influenza vaccines in the EU in the shortest possible time in case of a pandemic. The HSC endorsed a document on this matter at its meeting of 18-19 April 2005. The document recommends a partnership between the public sector and manufacturers on vaccine development and availability as part of a wider preparedness strategy which comprises the components that have been identified by the Council and the Commission.

The public sector would support industry by the development of a library of seed stocks for manufacturing of influenza vaccine, working together with the WHO collaborating laboratories to obtain new strains of influenza as they appear. 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, in collaboration with the European Pharmacopoeia. The time saved in having a vaccine available for public use by these activities is potentially 2 to 3 months and possibly more.

In tandem with the work of the partnership, the Member States are invited to push for an increase in their annual influenza vaccination coverage for their existing target groups, in line with the World Health Assembly resolution 56.19, which, apart from the immediate public health benefits, would also allow manufacturers' capacity to grow in interpandemic periods to facilitate sufficient pandemic influenza vaccine supply when the pandemic comes. Monitoring of vaccine uptake and immunisation status, as well as progress in achieving vaccination targets in each Member State should be undertaken under the auspices of the ECDC. The ECDC and the EMEA could join forces to monitor adverse effects and assist in establishing vaccine cost-effectiveness and public health benefits from extending coverage. The Commission will liaise with the vaccine manufacturers to evaluate progress towards vaccine production capacity increase and equity of supply in pandemic situations and to address, together with the Member States, questions of liability.

Funding of the work for the partnership could be provided through the EU Public Health Programme. Regulatory support is being provided to industry through existing mechanisms of cooperation in which EMEA plays a central role and through the waiving of fees for mock-up dossiers and scientific advice from the EMEA. The Commission, with advice from the ECDC, may develop proposals for Council recommendations for influenza vaccination.

The Commission proposed on 6 April a European Parliament and Council regulation to establish a solidarity fund that would allow for reimbursement of costs up to 1000 million euros annually that might be incurred in a major public health emergency, which covers costs on vaccines and antivirals. EU Member States will be reimbursed following a proposal by the Commission and a favourable decision taken by qualified majority by the Council. This could act as an incentive for the Member States to conclude advance purchase agreements with the industry if they so wish and help contributing towards the creation of conditions of equity of supply.

- *Antivirals*

For antivirals an approach similar to the one for vaccines is being undertaken and a meetings have taken place to discuss availability of antivirals in different forms and in particular the supply difficulties experienced by several Member States. The EMEA, on Commission's request, has reviewed antivirals on the market and produced extensive guidance which was communicated to the Member States' authorities to aid them in decisions on procurement and use. The efforts undertaken in this area have led to insights by Member States on the acquisition of antivirals, their use and limitations and stimulated an interest in the pharmaceutical industry for involvement of more companies, which would undoubtedly benefit Member States and public health in general. The Commission, together with the HSC, is pursuing discussions with the industry.

ANIMAL HEALTH ASPECTS

In order to prevent the introduction of the avian influenza virus from the Asian countries where the outbreak is ongoing, imports of live birds and risky poultry products such as fresh poultry meat and untreated feathers have been prohibited under Commission Decision 2004/122/EC. The situation in Asia is regularly reviewed at the Standing Committee on the Food Chain and Animal Health, where the safeguard measures taken are updated, as appropriate. Furthermore, in coordination with the Food and Agriculture Organisation, the World Organisation for Animal Health (OIE) and the WHO, some emergency technical and financial support has been given to the countries affected, Vietnam in particular, and further actions are planned, including the training of official veterinarians and laboratory experts. Community co-financed programmes for the surveillance of avian influenza in poultry and wild birds have been completed in all Member States in accordance with Commission Decision 2004/630/EC. The Commission is also in the process of adopting a further Decision to co-finance the surveillance plans that the Member States will carry out in 2005-2006.

The Commission put forward in April 2005 a proposal for a Council Directive on Community measures for the control of avian influenza that updates current rules and repeals current Directive 92/40/EEC. This proposal aims at ensuring that Member States apply the most appropriate surveillance and control measures against avian influenza and so reduce the risk of major outbreaks of the disease and encourages closer collaboration between veterinary and public health authorities in the Member States.

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