



COUNCIL OF
THE EUROPEAN UNION

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Council Conclusions on Pandemic (H1N1) 2009 – a strategic approach

***2965th EMPLOYMENT, SOCIAL POLICY, HEALTH AND
CONSUMER AFFAIRS Council meeting***

Luxembourg, 12 October 2009

The Council adopted the following conclusions:

“On 11 June 2009 the World Health Organisation (WHO) raised the level of influenza pandemic alert from phase 5 to phase 6, which corresponds to the worldwide spread of the virus Influenza A (H1N1) 2009. On the basis of scientific and epidemiological data and knowledge the WHO and the European Centre for Disease Prevention and Control (ECDC) are advising countries in the northern hemisphere to prepare for a new wave of the pandemic.

Therefore, the Council of the European Union:

1. **RECALLS** the WHO’s International Health Regulations (IHR 2005), Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for epidemiological surveillance and control of communicable diseases in the Community¹ and the Early Warning and Response System for Communicable Diseases (EWRS) and Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control²;
2. **RECALLS** Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93, and in particular Articles 7 and 8. **NOTES** that specific legal provisions exist which provide flexibility on the extent of data requirements and provide for an accelerated authorisation of influenza vaccines after the declaration of the pandemic, and that the Commission has authorised several influenza vaccines which would need to be varied in response to a concrete pandemic situation;

¹ OJ L 268/1, 3.10.1998

² OJ L 142, 30.4.2004

3. **WELCOMES** the efficiency of the work of the European Medicines Agency (EMEA) in providing its opinion on the first three vaccines and the diligence of the Commission in delivering their marketing authorisations;
4. **RECALLS** the Council Conclusions of 16 December 2008 on health security, in which the Member States are invited to continue and to extend cooperation on preparation, monitoring, early warning and coordinated responses for all matters relating to public health emergencies involving more than one Member State;
5. **RECALLS** the Council Conclusions of 30 April 2009 on influenza A(H1N1) Infection, in which the Member States are urged to continue to act together under the guidance of the WHO and in cooperation and in liaison with the Commission;
6. **RECALLS** the structures in place for informal cooperation and coordination on health threats, notably the Health Security Committee (HSC) established in 2001 by Health Ministers and the European Commission that issued a shared approach in three statements on school closures, symptomatic individuals travelling and on targets and priority groups for vaccination;
7. **RECOGNISES** the important work undertaken by the UN system, in particular the WHO, the Senior UN System Coordinator for Avian and Human Influenza and the World Bank in their activities to support third countries;
8. **RECALLS** the recommendations of the Strategic Advisory Group of Experts on Immunization (SAGE), endorsed by the WHO on 11 July, relating to vaccines for the Pandemic (H1N1) 2009 in order to achieve the following three objectives of a vaccination strategy: protect the integrity of the healthcare system and the country's critical infrastructure, reduce morbidity and mortality and reduce transmission of the influenza A(H1N1) 2009 virus within communities;
9. **RECALLS** the discussion at the Informal Health Ministerial meeting in Jönköping on 6 and 7 July 2009, in which possible elements for a strategic approach at EU level were addressed;
10. **RECOGNISES** that different conditions in Member States may require country-specific approaches and that Member States do not need necessarily to take the same actions as identified inter alia in the summary of the proceedings of the Presidency meeting on Pandemic Influenza held in Jönköping on 2 and 3 July 2009;
11. **WELCOMES** the work by the ECDC and the EMEA to support and provide scientific advice and guidance to the Member States and the Commission on issues related to influenza as well as the activities of the HSC;
12. **TAKES NOTE** of the Commission Communication on Pandemic (H1N1) 2009³ as an important contribution to the ongoing pandemic response;

³ COM(2009) 481 final

13. **RECOGNISES** the need for the Member States to take all appropriate measures to ensure the most efficient protection of citizens, based on the most recent scientific evidence and drawing on consultations at European level and with the WHO, and taking account of developments in the epidemiological situation;
14. **NOTES** that the preparations for, and response to, health risks in the EU falls within the competence of the Member States and that public health measures can be supported and enhanced by further cooperation and sharing of information and experiences through the WHO and existing EU structures;
15. **EMPHASISES** that the effectiveness of national measures is further enhanced by cooperation and coordination measures taken by the Commission and the Member States with the assistance of the ECDC and the EMEA and in cooperation with the WHO;
16. **EMPHASISES** the need for Member States to work together on multi-sectoral issues, notably transport, energy and information and telecommunication sectors, in order to mitigate the possible economic and social impact of this and future pandemics and other similar health threats;
17. **RECALLS** that Member States (and third countries) confronted with a major emergency that overwhelms their national response capability can, at any time, activate the Community Mechanism for Civil Protection;
18. **AGREES** that the following key issues should be part of a coordinated EU approach towards Pandemic (H1N1) 2009:

Availability of vaccines

To ensure timely availability of vaccines for all Member States, the possibility of a mechanism or a bundle of tender notices should be considered by those Member States with no current or with partial agreements with manufacturers as the most efficient way to proceed.

Subject to clarification of legal issues, such as those relating to competition law and liability Member States that already have arrangements with manufacturers might wish to consider making vaccines available to other countries.

Vaccination strategy

The target groups encompass all people to whom vaccination should be recommended according to national plans.

As there will not initially be sufficient vaccines available, Member States should identify priority groups for vaccination. The identification of these priority groups should be based on the evolving scientific evidence and risk-benefit analysis and will depend upon country-specific conditions. On 25 August 2009, the HSC, taking into account the current epidemiological and scientific information and knowledge on the Pandemic (H1N1) 2009, proposed three groups for first-priority vaccination⁴.

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- All persons from the age of 6 months with underlying chronic conditions increasing the risk for severe disease, starting with those who have a severe underlying condition (e.g. severe asthma,

The regulatory process

Robust regulatory procedures, including a thorough risk-benefit analysis by a competent and independent body, are in place to have efficient, safe and high-quality vaccines available across the EU. It will be essential to swiftly assess additional data as they become available and to closely monitor for any unexpected serious adverse reactions to allow for reassessment of the risk-benefit ratio where necessary. Close cooperation between Member States, the EMEA and the ECDC, as well as post-marketing surveillance including pharmacovigilance and risk-management plans, are therefore important.

Information and communication to the public

Communication with the public, media and other parties in one Member State or by the Commission may have an impact across the Member States. Conflicting messages should be avoided wherever possible and the parties should when necessary engage in continuous trust-building and sharing of key lines of messages to the media, in order to minimise possible unwanted social and economic consequences.

To ensure consistency of information, agreements on common key strategic lines on important issues should be considered when needed. These could address issues of common interest such as the level of risk posed by the virus, what challenges the Member States could face due to the pandemic, actions already taken and actions to be taken, and the importance of measures for individuals to protect themselves. Such common key strategic lines should be based on scientific advice from the WHO and the ECDC, bearing in mind the country-specific circumstances such as the evolution of the pandemic.

Global cooperation

As the Pandemic (H1N1) 2009 is a global problem, the EU reiterates its commitment to support global cooperation, under the auspices of the UN system, carried out in close cooperation with the WHO.

Multi-sectoral issues

Pandemics may have an impact on productivity and the ability to maintain the continuity of essential services in the Member States. To avoid any disruption in transportation (of food, pharmaceuticals, fuel etc.), communications and energy supply, the Member States will work together on multi-sectoral coordination at many different levels, as appropriate:

- Pandemic preparedness is a responsibility which is shared amongst many different actors. This situation calls for coordination and information-sharing at the strategic and operational levels within the existing structures and without duplicating the work of existing EU-level groups and mechanisms at the EU level dealing with the various aspects of the Pandemic (H1N1) 2009;

unstable coronary heart disease, uncompensated heart failure, etc.), the proposal optimally being made by the patient's direct healthcare provider;

- pregnant women;
- healthcare workers.

- Existing measures and arrangements to ensure the functioning of critical services should be reviewed and the needs analysed, in the first instance, in the information and telecommunication, transport and energy sectors with a view to possible further arrangements. These sectors include a number of transnational service operators with regional or EU-wide business coverage as well as business continuity planning. Interdependence within these sectors and other sectors may give rise to a need for enhanced information exchange and collective action at EU level as the pandemic develops.

19. INVITES THE MEMBER STATES AND THE COMMISSION TO

Information and communication to the public

- identify possible common strategic lines to take in order to ensure coherent information through experts of the HSC and further elaborate through the communicators network of the HSC.

Multi-sectoral issues

- cooperate in the exchange of strategic and operational information on multi-sectoral issues.

Global cooperation

- explore ways to support immediate efforts of the UN system and in particular of the WHO in mitigating the Pandemic (H1N1) 2009, including the provision and adequate distribution and access to vaccines and antivirals but also consider the need for contingency planning and public health campaigns and develop and agree on a position in response to the UN, WHO and UNSIC Needs Assessment Report⁵ in a way that does not negatively affect other global health priorities;
- effectively use existing financial and other (e.g. logistical, know-how support) European Union mechanisms for the benefit of third countries, in particular developing countries, and global cooperation;
- maintain strong support in assisting developing countries to develop sustainable public health systems;
- encourage broader production and use of influenza vaccines including the use of new innovative technologies in order to increase the global production of vaccines and capacity building in developing countries so that they can develop their own vaccines and antivirals.

20. INVITES THE COMMISSION TO:

Availability of vaccines

- continue to support procurement processes for the vaccine for those Member States, candidate countries, potential candidates and neighbouring countries who do not have a current agreement with manufacturers;

⁵ Urgent Support for Developing Countries' Responses to the H1N1 Influenza Pandemic of 17 September 2009 [WHO, Office for the Coordination of Humanitarian Affairs (OCHA), UN System Influenza Coordination (UNSC)]

- propose transparent mechanisms whereby a Member State willing to do it can make available vaccines to another Member State in order to address the shortage of safe vaccine in one Member State and provide clarity on issues of Community law related to the transfer of vaccines between the Member States, such as those relating to competition law and liability;
- report on the availability mechanisms for vaccines, their operations and results as well as future cooperation initiatives.

The regulatory process

- ensure that procedures for the risk-benefit assessment and the adoption of formal decisions on marketing authorisations for vaccines continue to be as swift and rigorous as possible;
- promote close cooperation between the Member States, the EMEA and the ECDC on post-authorisation aspects, such as pharmacovigilance and surveillance.

Information and communication to the public

- continue to facilitate cooperation on common approaches for communication through the communicators network of the HSC;
- explore suitable ways to support the communication activities of the Member States where such support may be appropriate.

Multisectoral issues

- report on the national planning assumptions used by each Member State for the Pandemic (H1N1) 2009;
- explore the potential value of developing guidance / principles / toolkits for business continuity planning at EU level;
- provide an overview of existing Community provisions and Member States capacities for managing cross-border, intersectoral and transboundary disruptions resulting from a pandemic, initially in the information and telecommunication, transport and energy sectors;
- update the Communication from the Commission on pandemic influenza preparedness and response planning in the European Community of 28 November 2005⁶.

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COM(2005) 607final