



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 28 July 2010

12665/10

SAN 158

“I/A” ITEM NOTE

from: Working party on public health
to: Permanent Representatives Committee (Part 1)/Council

No. prev. doc.: 12483/10 SAN 156

Subject: Lessons to be learned from the A/H1N1 pandemic - Health security in the
European Union
- Adoption of Council conclusions

On 27 July 2010 and following a number of meetings, the Working party on public health agreed on the draft Council conclusions as set out in the Annex.

Subject to confirmation by the Permanent Representatives Committee (Part 1), the Council is invited to agree on the draft Council conclusions at its meeting on 13 September 2010.

**Draft Council Conclusions on
Lessons learned from the A/H1N1 pandemic – Health security in the European Union**

The Council of the European Union

1. RECALLS that under Article 168 of the Treaty on the Functioning of the European Union, Union action is to complement national policies and be directed towards improving public health; it is also to encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action, and fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care;

**REGARDING THE LESSONS LEARNED FROM THE INFLUENZA PANDEMIC
A(H1N1),**

2. NOTES the rapid and robust response of the Member States, the European Commission, the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA) and the World Health Organization (WHO) to the outbreak of the influenza Pandemic A(H1N1);

3. RECALLS the Council conclusions of 30 April 2009 on influenza A(H1N1) infection¹ in which the Member States were urged to work together and the Council conclusions of 12 October 2009 on Pandemic (H1N1) 2009 - a strategic approach²;

4. RECALLS the work undertaken within the framework of the Friends of the Presidency Group on pandemic influenza and during the technical workshop on “Multisectoral issues during crisis: an influenza pandemic as an example”, held in Brussels, Belgium, on 29 and 30 April 2010;

5. RECOGNISES that the EU needs to stay alert and prepared while continuing to critically review its response;

¹ 9392/09
² 13635/09

6. WELCOMES the Stakeholder consultation on strengthening EU Preparedness on Pandemic Influenza launched on 27 May 2010 as well as the different evaluations performed by the Commission and the Member States;

7. WELCOMES the Conference “Lessons learned from the A(H1N1) pandemic”, held in Brussels on 1 and 2 July 2010, which dealt with the issues of surveillance, medical measures, multisectoral aspects and communication and which emphasized the efforts made by Member States, the Commission and its agencies, but also stressed the need for improved collaboration, as set out in the conclusions of the Conference given in the Annex;

8. RECALLS the discussion at the Informal Health Ministerial Meeting in Brussels on 5 and 6 July 2010, in which measures for improved cooperation were discussed;

9. RECOGNISES that while pandemic preparedness and response planning as well as implementation remain primarily a matter of national competence to be decided on by Member States, it is necessary to enhance the coordination of these national measures at EU level;

10. EMPHASISES the importance of the assistance of the ECDC and the EMA and also cooperation with the WHO in further cooperation and coordination at EU level;

REGARDING HEALTH SECURITY IN THE EU,

11. RECALLS that the Health Security Committee (HSC) was established as an informal cooperation and coordination body by the Health Ministers, supported by the Commission, based on the Declaration of the Heads of State in Ghent in 2001, on health-related threats from acts of terrorism or any deliberate release of biological or other agents with the intent to harm health;

12. RECALLS the Council conclusions of 22 February 2007 on the transitional prolongation and extension of the mandate of the HSC with a view to a future general revision of the structures dealing with health threats at EU level³, in which the mandate of the HSC was extended to include pandemic preparedness and response as well as coordination of emergency planning at EU level and to contribute to the implementation of the International Health Regulations - IHR (2005). These Council conclusions also requested a review of the HSC mandate, in any case at the latest within two years after the submission of the report on the achievements of the ECDC to the European Parliament and the Council, as envisaged in Article 31 of Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004;

13. RECALLS the Council conclusions of 16 December 2008⁴ which invited the Commission to present, in 2010, a communication proposing a long-term solution for the EU framework for health security taking into account the existing structures in all relevant sectors and the need to avoid duplication accompanied, where appropriate, by a legislative proposal and to adapt the status of the HSC to the health challenges of the future, taking account of the mandate of the ECDC and the entry into force of the IHR(2005);

14. NOTES the Commission Communication of 17 November 2008 "The ECDC activities on communicable diseases: the positive outcomes since the Centre's establishment and the planned activities and resource needs"⁵;

15. STRESSES the important role of the HSC in coordination and collaboration, between the Member States, in line with the IHR(2005), to ensure cooperation with all sectors, and with existing structures;

16. AGREES to:

- temporarily prolong, until the long-term solution envisaged in paragraph 19 is put in place, the mandate of the HSC as a cooperation and coordination body for the Member States, supported by the Commission, according to the terms of reference outlined in the Council conclusions of 2007;

³ 5862/07

⁴ 16515/08

⁵ 15832/08

17. INVITES Member States to:

- further improve their coordination and collaboration in facing public health emergencies of international concern within the EU, as defined in the IHR(2005), including pandemic influenza, and ensure appropriate representation in the HSC;
- further improve the coordination of public communication through the HSC communicators network on any matter related to public health emergencies involving more than one Member State and ensure a direct link between the HSC representative and the HSC communicator;
- ensure an appropriate surveillance and analysis capacity for health threats, both during and in between emergencies, and ensure immediate sharing of information through the relevant structures;

18. INVITES Member States and the Commission to:

- examine, on the basis of a consultation paper from the Commission, options for the legal basis of the HSC to support the Council in achieving a coherent approach to preparedness for and response to health threats and especially public health emergencies of international concern as defined in IHR (2005);
- base their approaches on solid independent scientific risk assessment;
- consider working together on joint procurement and common approaches to contract negotiations for medicinal products;

19. INVITES the Commission to:

- revise the Pandemic Preparedness Plan of the EU⁶, taking into account lessons learned from the A(H1N1) pandemic, the national and European evaluations concerned and in coherence with the WHO review of the IHR(2005) and the international framework, giving particular attention to the need for inter-sectoral preparedness for a pandemic and to reducing the impact of a pandemic on society, to ensure that the response is flexible, proportionate and adapted to the severity of the threat;
- report on and develop, as soon as possible and no later than December 2010, a mechanism for joint procurement of vaccines and antiviral medication which allows Member States, on a voluntary basis, common acquisition of these products or common approaches to contract negotiations with the industry, clearly addressing issues such as liability, availability and price of medicinal products as well as confidentiality;
- improve the fast registration procedure for vaccines, as regards, inter alia, making it suitable for different influenza strains, varying levels of severity and differences in target population groups, the format and content of the application for marketing authorization, the requirements on packaging and leaflets, the availability of data from clinical trials, the scientific pre- and post marketing evaluation and transparency of communication on the procedure whilst safeguarding the quality, safety and efficacy of the vaccines;
- present, in 2011, a proposal for a long-term solution for health security taking into account the outcome of the examination of the options for the legal basis of the HSC referred to above and the existing structures in all relevant sectors and the need to avoid duplication of work, and in the interim, to ensure that the Council is regularly updated on the work of the HSC.

⁶ Communication from the Commission on pandemic influenza preparedness and response planning in the European Community of 28 November 2005

Conclusions of the
Conference on lessons learned from the A(H1N1) pandemic
Brussels, 1 and 2 July 2010

Context

As the incoming Presidency of the European Union, Belgium, in cooperation with the European Commission, organised a conference on lessons learned from the A(H1N1) pandemic. On 1 and 2 July, over 300 experts representing **ALL** of the Member States of the Union and European institutions, namely the Commission, the European Medicines Agency and the European Centre for Disease Prevention and Control as well as the World Health Organization took part in that conference. A number of representatives from the USA, Canada and the EU's candidate and/or neighbouring countries also travelled to Brussels to take part in the debates.

The European Parliament was also represented at the conference by representatives of the Committee on the Environment, Public Health and Food Safety.

The participants debated four major themes in a spirit of constructive criticism: surveillance, multi-sectoral aspects, communication and medical measures (antiviral medication and vaccines).

Conclusions

For the session on surveillance, the participants raised the following points:

1. In order, during epidemics, and also in other circumstances, to be able to have reliable figures on the number of cases, the severity of the disease, the at-risk groups, etc., it is necessary to continue to invest in national surveillance centres, both in the area of **epidemiological surveillance** on the number of people afflicted, deaths, etc., and in the area of **virological surveillance** on the genetic characteristics of the virus: mutations and resistance but also **serological surveillance** to be able to determine whether many cases are asymptomatic.
2. During periods of crisis there should be agreement in advance on a **minimum set of necessary data** to enable decision-making in order avoid excessive pressure on surveillance centres. The harmonisation of data within the European Union should be better prepared and integrated in national plans to be able to compare and share this data.
3. It is important to continue to increase investment in research to be able to **better assess and predict the impact of the influenza** both in the inter-pandemic period and at its very beginning. Functional mathematical models should be promoted and developed at the European level.
4. To be able to better communicate the risks and explain the thinking behind measures, it is necessary for sociologists to participate with scientists and communicators.

With regard to the session on the **multi-sectoral aspects**, the following conclusions were reached:

1. The pandemic **prompted the drawing up or updating** of companies' business continuity plans (BCPs).
2. The World Health Organization's International Health Regulations were acknowledged as an important and necessary tool. The development of the **national capacities** essential to their implementation in full remains a challenge and must be improved in the health sector and in the other sectors concerned.
3. A "**BCP for Dummies**" must be developed. It will explain in a generic, simple and flexible way how each company can prepare itself.
4. There is a need for better cooperation both between **social partners** (employers and employees), and between the **private and public sectors** not only in the context of preparation, but also for the implementation of the response.
5. The added value of the European Union could be important in filling in the gaps in knowledge and the common understanding of the **vulnerabilities and interdependencies** of the different socio-economic sectors in the event of a pandemic.

The session on **communication**, an important element in the context of crisis management, was debated with partners from the media. Together they arrived at the following conclusions:

1. The framework for communication between the Member States and the Commission was in place before the pandemic thanks to the creation within the Health Security Committee of the Communicators' Network. The **HSC Communicators' Network**, which played a key role in harmonising the Member States during the pandemic, sought to share the communication challenges with which the members were confronted, while providing support and advice to each other in the writing of common guidelines as well as in the development of the messages on key subjects. In decision-making on future policies, the HSC must take into account communication factors, which can be obtained through the collection of the comments, the feedback and the experiences of the HSC Communicators' Network. The existing tools available to the Network must be improved and adjusted (like HEDIS and Medisys).
2. Surveys of the members showed the possibility of using stakeholders and the media to communicate both to the population in general and to specific target groups. Identifying and establishing a relationship with stakeholders and the media before a pandemic is essential. Establishing **relationships of trust** with journalists before a crisis begins is judged to be essential to better guarantee good working relationships during a crisis. The existence of a **select group of available experts** to answer questions from journalists at all times, as well as the availability of a **spokesperson**, are factors that are both considered essential.

3. Although the “**at-risk**” groups had been identified, there was no pan-European **global strategic approach** on how to reach them and communicate with them. Global analyses of the target groups, including their use of the media, their consumer behaviour, the information sources they trust and which they consider credible, would be useful in order to develop key messages that are tailored and personalised for the respective target groups. Furthermore, polls and surveys are considered to be essential tools for understanding the perceptions and behaviours of our citizens in a health crisis. These methods make it possible to monitor changes in behaviour and, consequently, to assess whether we are passing on the right messages. A plan for conducting polls / surveys must be established before a crisis. The polling methods, the models and the results should be shared between countries as a source of information and the exchanging of good practices.

4. The use of **new social media** (Web 2.0) is increasing ever more rapidly and will offer new possibilities for reaching specific target groups. The possibility exists to monitor and analyse the activity of these groups and by so doing to spot the early warning signs of alarm and trends. The current trend should continue and cannot be ignored or left out of any communication plan. Social media is managed by the users and is a two-way form of communication. The institutions must get involved in these recent developments and learn to communicate “with” and not “to” the public so that there is rapid response. In this way, the key messages can be adjusted according to what is being said online.

During the session on **medical measures**, only the aspects relating to accelerated centralised registration mechanisms and vaccines and antiviral medications were addressed. Here are the participants’ conclusions:

1. There is a need for studies that are independent from the pharmaceutical companies on the vaccines and antiviral medications including for the monitoring of the vaccination coverage. To date we have been too dependent on the pharmaceutical companies for these studies.
2. It is necessary to define the **roles and relationships** between the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC), the national regulatory authorities and the public health authorities, as well as with the World Health Organization (WHO).
3. It is necessary to review **purchasing procedures** to include in them elements such as the flexibility necessary to adjust the quantities ordered to actual needs, to review the terms on the liability aspects, etc.
4. Seeking solutions for the **joint purchasing** of vaccines and antiviral medications must be explored to be able to ensure equitable access, at the lowest price. This joint approach should increase authorities’ negotiating power.
5. Communication to **health workers** must be improved. They must be more involved in the formulation and implementation of crisis response measures.



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SAN 159

“I/A” ITEM NOTE

from: Working party on public health
to: Permanent Representatives Committee (Part 1)/Council

No. prev. doc.: 12482/10 SAN 155

Subject: Action against cancer
- Adoption of Council conclusions

On 27 July 2010 and following a number of meetings, the Working party on public health agreed on the draft Council conclusions as set out in the Annex.

Subject to confirmation by the Permanent Representatives Committee (Part 1), the Council is invited to agree on the draft Council conclusions at its meeting on 13 September 2010.

Draft Council conclusions on action against cancer

The Council of the European Union

1. RECALLS that under Article 168 of the Treaty on the Functioning of the European Union, Union action is to complement national policies and be directed towards improving public health; it is also to encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action, and fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care;
2. RECALLS the Council conclusions of 10 June 2008 on reducing the burden of cancer;
3. TAKES NOTE of the Commission's Report of 22 December 2008 on the Implementation of the Council Recommendation of 2 December 2003 on cancer screening¹, that found that much has been done to attain high standards of screening practices across the Union, but that less than half the minimum number of recommended examinations is taking place if the screening tests specified in the Council Recommendation² were available to all Union citizens of appropriate age (approximately 125 million examinations per year), and that they are not always carried out within the organisational framework necessary to ensure thorough quality assurance;
4. WELCOMES the Commission Communication of 24 June 2009 on Action Against Cancer: European Partnership³ to support the Member States in their efforts to tackle cancer by providing a framework for identifying and sharing information, capacity and expertise in cancer prevention and control, and by engaging relevant stakeholders across the Union in a collective effort, and the launch of the European Partnership on 29 September 2009;

¹ 5021/09

² Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC)

³ 11516/09

5. NOTES that the European Partnership for Action Against Cancer (herein after "the Partnership") is set up around four priority areas, namely health promotion and early detection; identification and dissemination of good practice; cooperation and coordination in cancer research; and providing the comparable cancer information and data necessary for policy and action through benchmarking and WELCOMES the Commission's initiative of setting up a Joint Action to take the Partnership forward and the active participation of all Member States in the Joint Action;

6. UNDERLINES the importance of closing the gap in health and in life expectancy between and within Member States and elaborating comprehensive strategies or plans for cancer prevention and control and NOTES that studies have shown that there are still significant differences between Member States even if the total number of cancer plans is increasing;

7. INVITES Member States to:

- participate actively in the Partnership;
- develop and implement comprehensive cancer strategies or plans by the end of 2013;
- continue their efforts on health promotion and disease prevention, in particular on tobacco control policies and the promotion of healthy lifestyles;
- continue their efforts to achieve full implementation of screening programmes for breast, colorectal and cervical cancer in line with the Council Recommendation of 2 December 2003 on cancer screening and periodically evaluate the effectiveness of available screening programmes, including the technology used and the different organisational approaches, with a view to further enhancing quality;
- ensure population-based cancer registration, which can provide accurate and comparable data on the cancer burden;
- continue their efforts as regards access to screening, diagnosis, treatment and rehabilitation, and to medication, in particular to reduce existing health inequalities related to cancer;

8. INVITES the Commission to:

- regularly update the European guidelines for quality assurance in screening;
- provide the scientific and technical support needed for the successful implementation of the activities of the Partnership;
- at the end of the initial phase of the Partnership, to report to the Council on its achievements, in particular in the light of the key deliverables and outcomes set out in the Commission Communication of 24 June 2009, to identify gaps and to consider the need for further action;

9. INVITES Member States and the Commission to:

- continue their efforts as regards research, in particular by collaborating in a more cohesive manner on transnational and translational cancer research and by promoting innovation;
- continue their efforts in the field of cancer prevention and control and renew their engagements as regards the follow-up to the Council conclusions of 10 June 2008 on reducing the burden of cancer⁴.

⁴ 9636/08