



| Basic information | |
|---|---------------------|
| 2010/2153(INI) INI - Own-initiative procedure Evaluation of the management of H1N1 influenza in 2009-2010 in the EU Subject 4.20.01 Medicine, diseases 4.20.06 Health services, medical institutions 4.20.07 Medical and para-medical professions | Procedure completed |

| Key players | | | |
|---------------------|--|---|------------------|
| European Parliament | Committee responsible | Rapporteur | Appointed |
| | <div style="border: 1px solid red; display: inline-block; padding: 2px;">ENVI</div> Environment, Public Health and Food Safety | RIVASI Michèle (Verts/ALE) | 14/07/2010 |
| | | Shadow rapporteur DELVAUX Anne (PPE) MCAVAN Linda (S&D) LEPAGE Corinne (ALDE) YANNAKOUDAKIS Marina (ECR) | |
| European Commission | Commission DG | Commissioner | |
| | Health and Food Safety | DALLI John | |

| Key events | | | |
|------------|--|---|---------|
| Date | Event | Reference | Summary |
| 09/09/2010 | Committee referral announced in Parliament | | |
| 25/01/2011 | Vote in committee | | Summary |
| 09/02/2011 | Committee report tabled for plenary | A7-0035/2011 | |
| 07/03/2011 | Debate in Parliament |  | |
| 08/03/2011 | Decision by Parliament | T7-0077/2011 | Summary |
| 08/03/2011 | Results of vote in Parliament |  | |
| 08/03/2011 | End of procedure in Parliament | | |

| Technical information | |
|----------------------------|--------------------------------|
| Procedure reference | 2010/2153(INI) |
| Procedure type | INI - Own-initiative procedure |
| Procedure subtype | Initiative |
| Legal basis | Rules of Procedure EP 55 |
| Other legal basis | Rules of Procedure EP 165 |
| Stage reached in procedure | Procedure completed |
| Committee dossier | ENVI/7/03231 |

| Documentation gateway | | | | |
|---|-----------|------------------------------|------------|-------------------------|
| European Parliament | | | | |
| Document type | Committee | Reference | Date | Summary |
| Committee draft report | | PE450.913 | 15/10/2010 | |
| Amendments tabled in committee | | PE454.473 | 20/12/2010 | |
| Committee report tabled for plenary, single reading | | A7-0035/2011 | 09/02/2011 | |
| Text adopted by Parliament, single reading | | T7-0077/2011 | 08/03/2011 | Summary |
| European Commission | | | | |
| Document type | | Reference | Date | Summary |
| Commission response to text adopted in plenary | | SP(2011)5426 | 12/09/2011 | |

Evaluation of the management of H1N1 influenza in 2009-2010 in the EU

2010/2153(INI) - 08/03/2011 - Text adopted by Parliament, single reading

The European Parliament adopted a resolution on the evaluation of the management of H1N1 influenza in 2009-2010 in the European Union.

The resolution recalls that according to the figures provided by the European Centre for Disease Prevention and Control (ECDC) at the end of April 2010, influenza A(H1N1) 2009 caused 2 900 deaths in Europe. These figures are low in comparison to the official mortality estimates for seasonal influenza, which the Commission put at 40 000 deaths in a moderate year and 220 000 in a particularly severe season. They are also significantly less than the most optimistic forecasts suggested by the health services of the EU Member States.

On the basis of the WHO pandemic alert and subsequent recommendations, the Member States responded rapidly using what resources they had available to implement public health action plans. The move to the highest level of alert, indicating the presence of a pandemic, gave rise in some cases to public health decisions that were disproportionate.

The following recommendations are made:

Enhanced cooperation: Parliament calls for the **prevention plans** established in the EU and its Member States for future influenza pandemics to be revised in order to gain in effectiveness and coherence and to make them sufficiently autonomous and flexible to be adapted as swiftly as possible and on a case-by-case basis to the actual risk, based on up-to date relevant information. It requests clarification, and if necessary review, of the **roles, duties, remits, limits, relationships and responsibilities of the key actors** and structures at EU level for the management of medical threats and that this information be made available to the public. The resolution emphasises the need to reinforce cooperation between Member States, and coordination of Member States with the European Centre for Disease Prevention and Control (ECDC).

Members express its approval for the introduction of a procedure enabling the Member States to make **group purchases** of anti-viral vaccines and medicinal products on a voluntary basis.

They recall that according to current Union legislation on medicinal products, **liability** for the quality, safety and efficacy concerning the authorised indications of a medicinal product rests with the manufacturer. They call for full application of this rule by Member States in all contracts for the procurement of vaccines.

The resolution urges the WHO to **revise the definition of a pandemic**, taking into consideration not only its geographical spread but also its severity.

More independence: Parliament takes the view that the **European Centre for Disease Prevention and Control (ECDC)** has to exercise its powers as an independent agency to assess and communicate the severity of infection risk and be given adequate means for all its tasks.

The resolution underscores the need for **studies independent of the pharmaceutical companies** on vaccines and antiviral medications, including with regard to the monitoring of vaccination coverage.

According to Members, it is necessary to ensure that scientific experts have no **financial or other interests** in the pharmaceutical industry that could affect their impartiality. They request the development of a **European code of conduct** relating to the exercise of the function of a scientific expert in any European authority in charge of safety and of the management and anticipation of risks.

The Commission, along with the support of the EMA, is invited to **improve the accelerated authorisation procedures** for the placing on the market of medicinal products designed to respond to a health crisis, in such a way that proper clinical trials are carried out before a pandemic occurs.

Increased transparency: Parliament calls for an **assessment of the influenza vaccination strategies** recommended in the EU and applied in Member States, covering the efficacy of the vaccines, their risk-benefit balance and the different target groups recommended, with a view to safe and effective use.

Members call for a **summary report** about the information on the number of doses purchased and used in different Member States, as well as on the illness and the adverse effects of the vaccinations and anti-viral treatments against H1N1 to be prepared by the Commission, before 8 March 2012, based on information presented by the Member States. This resolution should be made publicly available as an important contribution to the review of the current pandemic influenza preparedness plans.

Parliament recognises that **conflicts of interest** among experts who advise European public health authorities lead to suspicions of undue influence. It considers that all conflicts of interest must be avoided. It calls for the declarations of interest of all experts who advise the European public health authorities to be published.

Lastly, the resolution insists on the need to communicate risks and benefits more clearly and transparently to the public. It underlines the necessity to arrive at a **coherent message** to the citizens as soon as a health hazard is evaluated (e.g. the nature of the virus, the nature of the risk, how best to prevent it and the risks and benefits of prevention and/or treatment). Parliament calls for a global European strategic approach for the so-called 'at-risk' groups on how to reach them and communicate with them in case of pandemics.