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

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The Committee on the Environment, Public Health and Food Safety adopted the own-initiative report drafted by Michèle RIVASI (Greens/EFA, FR) on the evaluation of the management of H1N1 influenza in 2009-2010 in the EU.

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: the committee calls for the **prevention plans** established in the EU and its Member States for future influenza pandemics to be **revised**. 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 report 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 report urges the WHO to **revise the definition of a pandemic**, taking into consideration not only its geographical spread but also its severity.

More independence: Members take 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 report 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: the committee 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.

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 shall be prepared by the Commission in the 12 months after the adoption of this Parliament resolution based on information presented by the Member States. This report should be made publicly available as an important contribution to the review of the current pandemic influenza preparedness plans.

Members recognise that **conflicts of interest** among experts who advise European public health authorities lead to suspicions of undue influence. They consider that all conflicts of interest must be avoided. They call for the declarations of interest of all experts who advise the European public health authorities to be published.

Lastly, the report 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).