42. Calls for the Commission's mandates for standardisation to be improved in order to allow the European standardisation organisations to develop European Standards fulfilling the technical requirements for which compliance with a political decision is achieved or evaluated; in this respect, considers that there is a need for better involvement and cooperation between the European Commission and the European standardisation organisations in the drafting process; bearing in mind that these organisations work on the basis of consensus, considers it crucial for the proper functioning of the system that political issues are dealt with at the policy-making level and not delegated to the European Commission, the standardisation bodies or any enforcement administrations;

43. Calls for the introduction of a procedure for formal objection to a standard, such as in Decision No 768/2008/EC, to be included in the GPSD; considers that the use of this procedure should be possible even before a standard is cited in the Official Journal of the EU, but should not be a substitute for Member States significantly increasing the involvement of their market surveillance authorities in the standardisation system;

44. Calls on the Commission and all stakeholders to guarantee the financial sustainability of the European standardisation system, including through public-private partnerships and through multiannual financial planning, since this is essential to ensure its effectiveness and efficiency;

45. Calls for the Commission to take further steps in coherence with the new legislative framework, so that the necessary revisions can be enhanced;

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46. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.

Management of H1N1 influenza

P7_TA(2011)0077

European Parliament resolution of 8 March 2011 on evaluation of the management of H1N1 influenza in 2009-2010 in the EU (2010/2153(INI))

(2012/C 199 E/02)

The European Parliament,

— having regard to Article 168 of the Treaty of the Functioning of the European Union,

— having regard to the International Health Regulations – IHR (2005) 2005 ([1]),

— having regard to the Commission communication of 28 November 2005 on pandemic influenza preparedness and response planning in the European Community (COM(2005)0607),

— having regard to the Council working document of 30 November 2007 on health security related matters ([2]),

— having regard to the Council Conclusions of 16 December 2008 on health security ([3]),

([1]) http://www.who.int/ihr/en/
([2]) http://register.consilium.europa.eu/pdf/en/07/st15/st15789.en07.pdf
([3]) http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lsa/104770.pdf

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— having regard to the ECDC interim guidance document on 'Use of specific pandemic influenza vaccines during the H1N1 2009 pandemic' ([1]),

— having regard to the WHO guidance document of April 2009 on pandemic influenza preparedness and response ([2]),

— having regard to the Council Conclusions of 30 April 2009 ([3]) on Influenza A/H1N1 infection,

— having regard to the exchange of views between the ECDC director and Parliament's Committee on the Environment, Public Health and Food Safety, which took place on 4 September 2009,

— having regard to the Commission communication of 15 September 2009 on Pandemic (H1N1) 2009 ([4]),

— having regard to the Commission Staff Working Document of 15 September 2009 on Joint procurement of vaccine against influenza A (H1N1) ([5]),

— having regard to the Commission Staff Working Document of 15 September 2009 on communicating with the public and the media on Pandemic (H1N1) 2009 ([6]),

— having regard to the Commission Staff Working Document of 15 September 2009 on support to third countries to fight the Influenza A (H1N1) ([7]),

— having regard to the Commission Staff Working Document of 15 September 2009 on the regulatory process for the authorisation of antiviral medicines and vaccines in the protection against Pandemic Influenza (H1N1) 2009 ([8]),

— having regard to the Commission Staff Working Document of 15 September 2009 on vaccination strategies against pandemic (H1N1) 2009 ([9]),

— having regard to the document entitled 'European Strategy for Influenza A/H1N1 – Vaccine Benefit-Risk Monitoring' of October 2009 ([10]),

— having regard to the Council Conclusions of 12 October 2009 on the Pandemic (H1N1) 2009 – a strategic approach ([11]),

— having regard to the Commission Staff Working Document of 23 November 2009 on Health Security in the European Union and Internationally ([12]),

([1]) http://www.ecdc.europa.eu/en/publications/Publications/0908_GUI_Pandemic_Influenza_Vaccines_during_the_H1N1_2009_Pandemic.pdf
([2]) http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html
([3]) http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/107492.pdf
([4]) http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/com481_2009_en.pdf
([5]) http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/flu_staff1_en.pdf
([6]) http://ec.europa.eu/health/ph_threats/com/Influenza/docs/flu_staff2_en.pdf
([7]) http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/flu_staff3_en.pdf
([8]) http://ec.europa.eu/health/ph_threats/com/Influenza/docs/flu_staff4_en.pdf
([9]) http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/index_en.htm#fragment2 and http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/flu_staff5_en.pdf
([10]) http://www.ema.europa.eu/docs/en_GB/document_library/Report/2010/01/WC500044933.pdf
([11]) http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/110500.pdf,
([12]) http://ec.europa.eu/health/preparedness_response/docs/commission_staff_healthsecurity_en.pdf

— having regard to the Assessment Report of 16 April 2010 on EU-Wide Response to the Pandemic (H1N1) 2009 ([1]),

— having regard to the final report of January 2010 on the Evaluation of the European Medicines Agency ([2]),

— having regard to Resolution 1749 (2010) 'Handling of the H1N1 pandemic: more transparency needed' adopted by the Parliamentary Assembly of the Council of Europe in June 2010 ([3]),

— having regard to the conclusions of the Conference on lessons learned from the A (H1N1) pandemic, held on 1 and 2 July 2010 ([4]),

— having regard to the recommendations of the European Ombudsman concerning the European Medicines Agency of 29 April and 19 May 2010 ([5]),

— having regard to the Assessment Report of 25 August 2010 on EU-Wide Pandemic Vaccine Strategies ([6]),

— having regard to the Council Conclusions of 13 September 2010 on Lessons learned from the A/H1N1 pandemic – Health security in the EU ([7]),

— having regard to the Commission Staff Working Document of 18 November 2010 on lessons learnt from the H1N1 pandemic and on health security in the European Union (SEC(2010)1440),

— having regard to the Annual epidemiological report on communicable diseases in Europe 2010 by the ECDC ([8])

— having regard to the Workshop held on 5 October 2010 by the European Parliament's Committee on the Environment, Public Health and Food Safety on the Influenza Pandemic A (H1N1) - The response of Member States and the European Union,

— having regard to Rule 48 of its Rules of Procedure,

— having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0035/2011),

A. whereas the national and international health authorities, including the WHO, stated in May 2009 that the H1N1 influenza was at the time causing only mild illness, but that it could not be taken for granted that this pattern would continue,

B. whereas, under the International Health Regulations (IHR) – a legal instrument binding on the states parties to it – the remit of the WHO includes public health surveillance, coordinating international public health measures and, in relation to potentially pandemic viruses, determining current phases of alert on a scale of one to six,

([1]) http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/index_en.htm#fragment2
([2]) http://ec.europa.eu/health/files/pharmacos/news/emea_final_report_vfrev2.pdf
([3]) http://assembly.coe.int/Mainf.asp?link=/Documents/AdoptedText/ta10/ERES1749.htm
([4]) http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/116478.pdf
([5]) http://www.ombudsman.europa.eu/press/release.faces/fr/4940/html.bookmark and http://www.ombudsman.europa.eu/press/release.faces/fr/5251/html.bookmark
([6]) http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/index_en.htm#fragment2
([7]) http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/116478.pdf
([8]) http://www.ecdc.europa.eu/en/publications/Publications/1011_SUR_Annual_Epidemiological_Report_on_Communicable_Diseases_in_Europe.pdf

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C. whereas the phases of a global pandemic are determined in accordance with the provisions of the IHR and in consultation with other organisations and institutions and with the Member States affected,

D. whereas the criteria for defining a 'pandemic', as revised by the WHO in 2009, are based solely on the spread of the virus while disregarding the severity of the illness caused by it,

E. whereas Member States, the European Commission and external bodies such as the WHO should take into account the virulence of a future influenza outbreak as well as the propagation of the virus when making public health decisions which may affect public health and social policies in Member States,

F. considering the high degree of unforeseeability regarding the pandemic's severity and how it was going to unfold, and the possibility that the pandemic might worsen in Europe, as it did in 1918 and 1968,

G. whereas, on the basis of the WHO pandemic alert and subsequent recommendations, the Member States responded rapidly, in line with the precautionary principle, using what resources they had available to implement public health action plans; whereas 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,

H. whereas the WHO called an end to the state of alert concerning H1N1 influenza only in August 2010 (statement by the WHO Director-General of 10 August 2010 ([1]),

I. whereas, in accordance with the principle of subsidiarity, the preparation for and reaction to health risks in the European Union fall within the competence of the Member States; whereas the Treaty of Lisbon exhorts the Member States to strengthen cooperation, sharing of information and good practices within the framework of the WHO and the existing structures of the EU; whereas stronger coordination measures by the Commission, with the support of the ECDC and the EMEA within the framework of the International Health Regulation, reinforce the effectiveness of national measures,

J. whereas the pharmaceutical industry had to respond to a sudden, pressing and exponential demand for the supply of vaccines by the Member States; whereas the industry had to develop with very great urgency a new vaccine likely to be effective against the virus,

K. whereas the costs arising from the management of this crisis in the Member States were significant and could perhaps have been reduced by better cooperation between the Member States and better coordination between the Member States and ECDC,

L. whereas the expenditure committed by certain Member States to the response plans drawn up relates mainly to the purchase of vast quantities of vaccines and antiviral treatments, and whereas purchasing procedures led to concerns regarding compliance with rules on public procurement and transparency in some Member States,

M. whereas there were significant price disparities among the Member States that had prior purchase agreements for vaccines, based, among other factors, on the differentiated liability conditions of each agreement,

N. whereas lawsuits were taken in various Member States, alleging corruption and conspiracy on the part of civil servants in relation to contracts signed in summer 2009 between ministries of public health and manufacturers of H1N1 influenza vaccines,

([1]) http://www.who.int/mediacentre/news/statements/2010/h1n1_vpc_20100810/en/print.html

O. whereas, according to the Commission the reluctance of vaccine suppliers to bear full product liability may have contributed to reducing citizens' trust in vaccine safety; whereas confidence in vaccines against H1N1 influenza was also undermined by incomplete and contradictory communication on the benefits and risks of vaccination and the potential risks of H1N1 influenza to the public,

P. whereas the differing recommendations made within the EU and the Member States on the subject of the priority groups targeted for vaccination illustrate the significant uncertainties and diverging views surrounding the appropriate response to H1N1 influenza,

Q. whereas pandemic influenza preparedness planning relies to a great extent on vaccination strategies; whereas vaccination strategies should rely on three conditions to be successful: efficacy of the vaccine, a positive benefit-risk balance for the vaccine, and targeting of risk groups,

R. whereas there needs to be transparency about the fulfilment of these conditions,

S. whereas the vaccines' benefit-risk ratio has now been demonstrated in tolerance and immunogenicity studies based on actual use,

T. whereas there is a need for studies on vaccines and antiviral medications that are independent from pharmaceutical companies so as to have a balance between private and publicly funded studies,

U. whereas, in the event of a future influenza pandemic, more work needs to be done to improve the performance of influenza vaccines, especially for high risk groups and against drifted variants,

V. whereas, due to the early acquisition of vaccines and systematic vaccination strategies, especially among the most vulnerable groups, the EU was the best prepared region in the world; whereas, however, considerable differences emerged between the preparedness of EU Member States and the lack of genuine cooperation weakened the EU's overall preparedness,

W. whereas the limited cooperation among Member States, especially the lack of joint public procurement of vaccines, the lack of joint stockpiles, the lack of a solidarity and brokerage mechanism between Member States, and the absence of prior purchase agreements in several Member States were the main factors undermining the EU's better preparedness,

X. whereas despite the repeated requests made by the European Ombudsman to the European Medicines Agency (EMA), the documents held by the EMA relating to research protocols, clinical trials and the undesirable effects of medicinal products submitted to it for assessment are not always accessible to the public,

Y. whereas the information and communication concerning H1N1 influenza in 2009-2010 in the EU have demonstrated the crucial role played by the media in relaying public health precautions and recommendations, but also in emphasising selected aspects of the outbreak and its consequences, thus potentially altering public opinion perceptions and the public authorities' responses,

Cooperation

1. 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;

2. 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 – the European Commission, the ECDC, the EMA and the Member States, as well as more informal entities such as the Health Security Committee, the HEOF and the 'public health' group, composed of senior officials able to intervene in the decision-making process regarding the management of a health crisis – and calls for that information to be made publicly available;

3. Welcomes the fact that the Commission has committed itself to studying the possibility of a revision and a long-term reinforcement of the legal basis of the Health Security Committee;

4. Requests that special attention be paid to preparation between sectors within the framework of co-operation between Member States on the Health Security Committee;

5. Emphasises the need to reinforce cooperation between Member States, and coordination of Member States with the ECDC, so as to ensure coherent risk management in response to a pandemic in compliance with the International Health Regulation;

6. Calls for the continuation and improvement of cooperation and coordination among Member States, institutions and international and regional organisations, particularly in the early stages of a virus outbreak, in order to determine its severity and make appropriate management decisions;

7. Considers it advisable to reinforce the mandate of the Committee of Public Health, the action and role of which should be improved to provide better support for the Member States in achieving a coherent approach to preparedness for and response to public health threats and emergencies of international concern as defined in the IHR;

8. Urges the WHO to revise the definition of a pandemic, taking into consideration not only its geographical spread but also its severity;

9. Calls on the Member States to involve health professionals more closely at every stage in the preparation and application of strategies for preventing and combating pandemics;

10. Urges the European Union to allocate more resources to research and development regarding preventive measures in the field of public health care while conforming to its stated objective of allocating 3 % of European GDP to R&D; more specifically, calls for an increase in the investments dedicated to a better evaluation and anticipation of the impact of an influenza virus both between pandemics and at the beginning of a pandemic;

11. Calls for continued investment in national epidemiological, serological and virological surveillance centres;

12. Expresses 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, in order to obtain, for a given product, *inter alia*, equitable access, advantageous rates and flexibility for the order;

13. Recalls 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, and calls for full application of this rule by Member States in all contracts for the procurement of vaccines, as an important factor in maintaining/regaining citizens' trust in vaccine safety;

14. Requests, within the framework of the common and responsible management of the supply of vaccines, that consideration be given to the possibility of easing access for developing countries to vaccine products in the event of a pandemic;

Independence

15. 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;

16. Invites the ECDC, with input from the WHO, to contribute to reviewing best practice on national influenza preparedness plans, and to make recommendations on best practice in areas such as crisis management techniques, vaccination and communication strategies;

17. Demands that increased vigilance and complete transparency be assured with regard to the evaluation of, and reporting on, medicinal products recommended in the event of health emergencies, and more particularly in genuine pandemic situations;

18. Underscores the need for studies independent of the pharmaceutical companies on vaccines and antiviral medications, including with regard to the monitoring of vaccination coverage;

19. Wishes to ensure that scientific experts have no financial or other interests in the pharmaceutical industry that could affect their impartiality; requests 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; requires that each expert subscribe to the ethical principles of this code of conduct before taking up his or her duties;

20. Asks that experts who are involved in the pharmaceutical sector, while they may be consulted, should be excluded from decision-making;

21. Calls in particular on the European Commission, with the support of the EMA, to improve the accelerated authorisation procedures for the placing on the market of medicinal products designed to respond to a health crisis - *inter alia* by making them suitable for different influenza strains varying levels of severity and differences in target groups - in such a way that proper clinical trials are carried out before a pandemic occurs, in order to ensure a full assessment of the risk-benefit balance associated with the use of those medicinal products for the relevant target groups and to come up with corresponding legislative proposals where necessary;

Transparency

22. 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;

23. Calls on Member States to report the following information to the Commission before 8 September 2011:

a) on different vaccines and anti-viral treatments, respectively:

(i) the number of doses purchased,

(ii) the total expenditure for the purchase,

(iii) the number of doses actually used,

(iv) the number of doses placed in storage, sent back to the manufacturer and reimbursed, or sold to other Member States or third countries,

b) on the disease and side effects of vaccines and anti-viral treatment, respectively:

(i) the number of H1N1 infections,

(ii) the number of deaths due to H1N1 infections,

(iii) the number and nature of adverse effects reported due to vaccinations or and anti- viral treatment against H1N1,

24. Calls on the Commission, with the support of ECDC and EMA, to make a summary report about the information referred to in paragraph 23, broken down by Member State, before 8 March 2012 and to make it publicly available as an important contribution to the review of the current pandemic influenza preparedness plans;

25. Reminds the EMA of the regulatory requirement to make access available to all the documents relating to clinical trials, research protocols and undesirable effects of the medicinal products evaluated by its experts, including the vaccines and anti-viral drugs recommended as a means of combating H1N1 influenza; welcomes the new rules on access to documents adopted by the EMA in October 2010;

26. Recognises that conflicts of interest among experts who advise European public health authorities lead to suspicions of undue influence and harm the overall credibility of these public health authorities and their recommendations; considers that all conflicts of interest must be avoided;

27. Requests the adoption of a definition common to all European public health authorities of what constitutes a conflict of interest;

28. Calls for such conflicts of interest to be brought to Parliament's attention by means of an internal investigation carried out by the Committee on Budgetary Control with a view to determining whether payments to the aforementioned experts were made in a correct and transparent manner and whether the procedures normally employed by the European institutions to forestall such conflicts of interest were followed;

29. Calls for the declarations of interest of all experts who advise the European public health authorities to be published, including those of members of informal groups;

30. Is aware of the need to communicate risks and benefits more clearly and transparently to the public; underlines the necessity to arrive at a coherent message to the citizens as soon as a health hazard is evaluated; insists on the importance of consistent communication by the Member States regarding the informative contents of the message (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);

31. 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;

32. Calls for the building of relationships of trust with the media concerned with disseminating public health messages; requests the setting-up of a select group of available experts to answer questions from journalists at all times, as well as the availability of a spokesperson;

33. Stresses the need for accountability of information professionals and the prudence required in the processing of health information messages, *a fortiori* in the context of a pandemic;

34. Expects, in this regard, a more comprehensive collection and rapid submission of coherent data from national health monitoring authorities to competent EU authorities,

35. Considers it essential for the Commission and Member States to swiftly undertake the necessary revisions, including better vaccination and communication strategies, in order to build confidence in public health measures that seek to prepare and prevent pandemics;

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36. Instructs its President to forward this resolution to the Council, the Commission, the WHO and national parliaments.

Innovative financing at a global and European level

P7_TA(2011)0080

European Parliament resolution of 8 March 2011 on innovative financing at global and European level (2010/2105(INI))

(2012/C 199 E/03)

The European Parliament,

— having regard to the conclusions of the European Council of 17 June 2010 and the conclusions of the European Council of 11 December 2009,

— having regard to the minutes of the ECOFIN meeting of 19 October 2010 and to the report to the European Council quoted therein,

— having regard to the Belgian Presidency's programme, in particular the proposals on innovative financing,

— having regard to its resolution of 10 March 2010 on financial transaction taxes – making them work ([1]),

— having regard to its resolution of 20 October 2010 on the Financial, Economic and Social Crisis ([2]),

— having regard to its resolution of 22 September 2010 on European Supervisory Authorities ([3]) and, specifically, its resolutions of 22 September 2010 on the European Insurance and Occupational Pensions Authority ([4]), of 22 September 2010 on the European Banking Authority ([5]), of 22 September 2010 on the European Securities and Markets Authority ([6]), and of 22 September 2010 on macro-prudential oversight of the financial system and establishment of a European Systemic Risk Board ([7]),

— having regard to the Commission staff working document on innovative financing at a global and European level (SEC(2010)0409) and the Commission Communication on the taxation of the financial sector (COM(2010)0549), along with the accompanying staff working document (SEC(2010)1166),

— having regard to the proposal for a regulation of the European Parliament and of the Council on OTC derivatives, central counterparties and trade repositories (COM(2010) 0484),

([1]) OJ C 349 E, 22.12.2010, p. 40.
([2]) Texts adopted, P7_TA(2010)0376.
([3]) Texts adopted, P7_TA(2010)0336.
([4]) Texts adopted, P7_TA(2010)0334.
([5]) Texts adopted, P7_TA(2010)0337.
([6]) Texts adopted, P7_TA(2010)0339.
([7]) Texts adopted, P7_TA(2010)0335.