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REPORT

on evaluation of the management of H1N1 influenza in 2009-2010 in the EU (2010/2153(INI))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Michèle Rivasi

PR_INI

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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on evaluation of the management of H1N1 influenza in 2009-2010 in the EU (2010/2153(INI))

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[2],

– 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[3],

– having regard to the Council Conclusions of 16 December 2008 on health security[4],

– having regard to the ECDC interim guidance document on 'Use of specific pandemic influenza vaccines during the H1N1 2009 pandemic'[5],

– having regard to the WHO guidance document of April 2009 on pandemic influenza preparedness and response[6],

– having regard to the Council Conclusions of 30 April 2009[7] 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[8],

– having regard to the Commission Staff Working Document of 15 September 2009 on Joint procurement of vaccine against influenza A (H1N1)[9],

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[2] http://www.who.int/ihr/en/
[3] http://register.consilium.europa.eu/pdf/en/07/st15/st15789.en07.pdf
[4] http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lsa/104770.pdf
[5] http://www.ecdc.europa.eu/en/publications/Publications/0908_GUI_Pandemic_Influenza_Vaccines_during_the_H1N1_2009_Pandemic.pdf
[6] http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html
[7] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/107492.pdf
[8] http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/com481_2009_en.pdf
[9] http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/flu_staff1_en.pdf

– having regard to the Commission Staff Working Document of 15 September 2009 on communicating with the public and the media on Pandemic (H1N1) 2009[10],

– having regard to the Commission Staff Working Document of 15 September 2009 on support to third countries to fight the Influenza A (H1N1)[11],

– 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[12],

– having regard to the Commission Staff Working Document of 15 September 2009 on vaccination strategies against pandemic (H1N1) 2009[13],

– having regard to the document entitled 'European Strategy for Influenza A/H1N1 – Vaccine Benefit-Risk Monitoring' of October 2009[14],

– having regard to the Council Conclusions of 12 October 2009 on the Pandemic (H1N1) 2009 – a strategic approach[15],

– having regard to the Commission Staff Working Document of 23 November 2009 on Health Security in the European Union and Internationally[16],

– having regard to the Assessment Report of 16 April 2010 on EU-Wide Response to the Pandemic (H1N1) 2009[17],

– having regard to the final report of January 2010 on the Evaluation of the European Medicines Agency[18],

– 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[19],

– having regard to the conclusions of the Conference on lessons learned from the A (H1N1) pandemic, held on 1 and 2 July 2010[20],

– having regard to the recommendations of the European Ombudsman concerning the

[10] http://ec.europa.eu/health/ph_threats/com/Influenza/docs/flu_staff2_en.pdf
[11] http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/flu_staff3_en.pdf
[12] http://ec.europa.eu/health/ph_threats/com/Influenza/docs/flu_staff4_en.pdf
[13] 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
[14] http://www.ema.europa.eu/docs/en_GB/document_library/Report/2010/01/WC500044933.pdf
[15] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/110500.pdf,
[16] http://ec.europa.eu/health/preparedness_response/docs/commission_staff_healthsecurity_en.pdf
[17] http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/index_en.htm#fragment2
[18] http://ec.europa.eu/health/files/pharmacos/news/emea_final_report_vfrev2.pdf
[19] http://assembly.coe.int/Mainf.asp?link=/Documents/AdoptedText/ta10/ERES1749.htm
[20] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/116478.pdf

European Medicines Agency of 29 April and 19 May 2010[21],

– having regard to the Assessment Report of 25 August 2010 on EU-Wide Pandemic Vaccine Strategies[22],

– having regard to the Council Conclusions of 13 September 2010 on Lessons learned from the A/H1N1 pandemic – Health security in the EU[23],

– having regard to the Commission Staff Working Document of 18 November 2010[24] on lessons learnt from the H1N1 pandemic and on health security in the European Union,

- having regard to the Annual epidemiological report on communicable diseases in Europe 2010 by the ECDC[25]

– 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),

- 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,

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,

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

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[21] 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

[22] http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/index_en.htm#fragment2

[23] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/116478.pdf

[24] SEC (2010) 1440 final, http://ec.europa.eu/health/preparedness_response/docs/commission_staff_lessonsh1n1_en.pdf

[25] http://www.ecdc.europa.eu/en/publications/Publications/1011_SUR_Annual_Epidemiological_Report_on_Communicable_Diseases_in_Europe.pdf

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[26]),

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,

O. whereas, according to the Commission the reluctance of vaccine suppliers to bear full

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

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 - as regards making that information 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 ...*:

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,

* insert date six months after the adoption of this resolution

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 ...** and to make it publicly available as an important contribution to the review of the current pandemic influenza preparedness plans;

** insert date 12 months after the adoption of this resolution

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;

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

EXPLANATORY STATEMENT

"Unlike the avian virus, H1N1 presently causes mainly mild illness, with few deaths, outside the outbreak in Mexico. We hope this pattern continues."
Margaret Chan, Director-General of the World Health Organisation, 18 May 2009

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.

The moderate severity of H1N1 influenza was officially recognised by the WHO as early as May 2009, at a press conference given by Margaret Chan, the Head of the World Health Organisation (WHO) – which is to say one month prior to the WHO issuing a level-6 'pandemic' alert over H1N1.

Member States and European institutions accepted this maximum-level alert, triggering in some Member States a raft of measures that were very costly (e.g. the costs are put at EUR 1 300 million in Great Britain and EUR 990 million in France - compared to EUR 87 million against seasonal influenza), and in those cases disproportionate to the actual – and known – severity of H1N1 influenza. A majority in the committee stated that it was unforeseeable to predict how the virus would develop.

The rapporteur pointed to the case of Poland, where the government did not proceed to vaccination against H1N1, and where nevertheless the death rate was comparable to those countries which decided to go for national vaccination campaigns.

The WHO should urgently revise its definition to include the severity of a disease into its definitions on the stages of a pandemic to allow for more appropriate responses.

The European Union needs closer cooperation

The committee considered that better cooperation is needed in the response to pandemics. It called for a review of the prevention plans. It also called for a clarification and if necessary review of the roles and responsibilities of key actors, and for reinforced cooperation between Member States and coordination of Member States with ECDC.

It also supported the introduction of a procedure that would enable the Member States to make group purchases on a voluntary basis. The committee made it clear that manufacturers have to bear full liability for the authorised indications of their products and that this should be fully applied by Member States in all contracts for the procurement of vaccines.

The European Union needs greater independence

According to the rapporteur, the analysis of the management of H1N1 influenza in Europe highlights an underlying problem: a lack of independent evaluation by our national and/or European health authorities, and a resulting failure to adapt the public health measures, as best as possible and in real time, to the actual clinical and epidemiological statistics available. The strategies adopted in the European Union and the Member States derived from preparedness plans drafted in 2005 or 2007, in conjunction with the WHO. In the majority of the Member States, the policies on the purchasing of vaccines had already been laid down in advance purchase agreements signed back in 2007 with pharmaceutical companies. The stock 'pandemic' vaccines given to millions of people in Europe were the subject of an accelerated authorisation procedures, based in fact on studies and vaccine formulae produced at the time of the H5N1 virus, which also dated from the years 2005/2007.

When asked about the safety of the adjuvants in the 'pandemic' vaccines, Zsuzsanna Jakab, former head of the ECDC, responded on 29 September 2009 in a letter to the rapporteur that '*it is true that no vaccine has ever been authorized on so little data, but it is expected that extrapolation can be done from the previous experience with the same adjuvants but with different flu strains*'.

With ECDC, the EU has a dedicated agency with regard to the assessment of communicable diseases. ECDC should full apply its competences as an independent agency to assess and communicate the severity of infection risk and be given adequate means for all its tasks.

Various improvements to the accelerated authorisation procedure are needed to allow for a better assessment of vaccines in case of a pandemic.

Financing and upstream choices can play a decisive role in deciding whether a trial is successful or not. That is why there is a need for studies on vaccines and antiviral medications that are independent of the pharmaceutical companies, including as regards monitoring of the vaccination coverage.

The European Union needs greater transparency

The analysis of the EU's management of the H1N1 crisis also highlights another vital issue: that of the evaluation of the medicinal products recommended against influenza, and the way they are being used. The committee agreed that vaccination strategies should rely on three conditions to be successful: that the vaccine is efficacious, that it has a positive risk-benefit balance and that it is targeted to the risk groups. A report providing clarity on the number of vaccines purchased and used in the various Member States and on the disease and its side effects of vaccines and anti-viral treatments should be made by the Commission based on information by Member States. At the same time, an assessment of the influenza vaccination strategies recommended in the EU and applied in Member States against these criteria should be done.

Conflicts of interest immediately lead to suspicions of undue influence. All conflicts of interests need to be avoided. According to the rapporteur, at the very least, declarations of

interest of all experts that advise the European public health authorities have to be published.

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	25.1.2011
Result of final vote	+: 58 –: 2 0: 1
Members present for the final vote	János Áder, Elena Oana Antonescu, Kriton Arsenis, Pilar Ayuso, Paolo Bartolozzi, Sandrine Bélier, Sergio Berlato, Martin Callanan, Nessa Childers, Chris Davies, Bairbre de Brún, Anne Delvaux, Bas Eickhout, Edite Estrela, Jill Evans, Elisabetta Gardini, Gerben-Jan Gerbrandy, Julie Girling, Nick Griffin, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Jolanta Emilia Hibner, Dan Jørgensen, Karin Kadenbach, Christa Klaß, Holger Krahmer, Jo Leinen, Corinne Lepage, Linda McAvan, Radvilė Morkūnaitė-Mikulėnienė, Vladko Todorov Panayotov, Gilles Pargneaux, Antonyia Parvanova, Andres Perello Rodriguez, Sirpa Pietikäinen, Mario Pirillo, Pavel Poc, Vittorio Prodi, Anna Rosbach, Oreste Rossi, Dagmar Roth-Behrendt, Horst Schnellhardt, Richard Seeber, Theodoros Skylakakis, Bogusław Sonik, Catherine Soullie, Salvatore Tatarella, Sabine Wils, Marina Yannakoudakis
Substitute(s) present for the final vote	Philippe Juvin, Jiří Maštálka, Miroslav Mikolášik, Bill Newton Dunn, Alojz Peterle, Michèle Rivasi, Csaba Sándor Tabajdi, Marita Ulvskog, Kathleen Van Brempt, Elżbieta Katarzyna Łukacijewska
Substitute(s) under Rule 187(2) present for the final vote	Ioan Enciu