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2009 - 2014

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*Committee on the Environment, Public Health and Food Safety*

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**2010/0195(INI)**

19.1.2011

# **COMPROMISE AMENDMENTS**

## **1 - 23**

**Draft report**  
**Michèle Rivasi**  
(PE450.913v01-00)

Evaluation of the management of H1N1 influenza in 2009-2010 in the EU  
(2010/0195(INI))

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**XM**

*United in diversity*

**XM**

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**Compromise Amendment 1**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**

Compromise amendment replacing Amendments 74, 75 (first part) and 76-79

**Motion for a resolution**  
**Subheading 1 and Paragraph 1**

*Motion for a resolution*

*Amendment*

**INDEPENDENCE**

1. Calls for the prevention plans established in the EU and its Member States to be revised 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 not least on the latest scientific information available;

**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 on a case by case basis to the actual risk, based on *up-to date relevant* information;

Or. en

**Consolidated Amendment 2**  
**Greens/EFA-EPP-S&D-ALDE-GUE/NLG**

Compromise amendment replacing Amendments 90-95

**Motion for a resolution**  
**Paragraph 2**

*Motion for a resolution*

*Amendment*

2. Takes the view that the powers of the European Centre for Disease Prevention and Control (ECDC) should be reinforced so that the EU has its own means of assessing the severity of infection risk, by establishing, if necessary, its own health alert scale independent of international organisations such as the WHO;

**INDEPENDENCE**

4. Takes the view that the European Centre for Disease Prevention and Control (ECDC) *has to 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*;

*4a. Invites the ECDC, with input from 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;*

Or. en

**Compromise Amendment 3**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**  
Compromise amendment replacing Amendments 96-99

**Motion for a resolution**  
**Paragraph 3**

*Motion for a resolution*

3. Demands that robust, credible and effective scientific procedures be introduced for the evaluation of medicinal products recommended in the event of health emergencies, and more particularly in genuine pandemic situations;

*Amendment*

5. Demands *that increased vigilance and complete transparency on* the evaluation of, *and the reporting on* medicinal products recommended in the event of health emergencies, and more particularly in genuine pandemic situations, *be implemented;*

Or. en

**Compromise Amendment 4**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**  
Compromise amendment replacing Amendments 101-108

**Motion for a resolution**  
**Paragraph 4**

*Motion for a resolution*

4. Calls for immediate clarifications on the effectiveness of the influenza vaccination strategies recommended in the EU, given the weight of evidence casting doubt on their effectiveness, the absence of reliable data guaranteeing that effectiveness and the lingering uncertainties surrounding their benefit-risk profile;

*Amendment*

**TRANSPARENCY**

7. 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 regard to a safe and effective use;*

**Consolidated Amendment 5**  
**Greens/EFA-EPP-S&D-ALDE-GUE/NGL**

Compromise amendment replacing Amendments 31 (second part), 109

**Motion for a resolution**  
**Paragraph 6a (new)**

*Motion for a resolution*

*Amendment*

***7a. 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 people that died due to H1N1 infections,***

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

***7b. Calls on the Commission, with the support of ECDC and EMA, to make a summary report about the information referred to in Paragraph 4a broken down by all Member States before ...\*\* and to make it publicly available as an important contribution for the review of the current pandemic influenza preparedness plans;***

***\* insert date six months after the adoption of this resolution***

**Consolidated Amendment 6**  
**Greens/EFA-EPP-S&D-ALDE-GUE/NLG**  
 Compromise amendment replacing Amendments 111-116

**Motion for a resolution**  
**Paragraph 5**

*Motion for a resolution*

5. Calls in particular on the EMA to review the accelerated authorisation procedures for the placing on the market of medicinal products designed to respond to a health crisis, in order to ensure correct assessment of the benefit-risk profile associated with the use of those medicinal products;

*Amendment*

6. Calls in particular on ***the European Commission with the support of*** 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 it suitable for different influenza strains, varying levels of severity and differences in target groups so that proper clinical trials have been 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;***

**Compromise Amendment 7**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**  
 Compromise amendment replacing Amendments 121-122-123-124

**Motion for a resolution**  
**Paragraph 6**

*Motion for a resolution*

TRANSPARENCY

6. Calls on the Commission to launch an audit of the operation of the EMA and the ECDC, and of the overall cost of the management of H1N1 influenza in the EU;

*Amendment*

*delete*

*delete*

**Compromise Amendment 8**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**  
Compromise amendment replacing Amendments 125-127

**Motion for a resolution**  
**Paragraph 7**

*Motion for a resolution*

7. Reminds the EMA of the regulatory requirement to make access available to all the documents relating to clinical trials, research protocols and the 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;

*Amendment*

**8.** Reminds the EMA of the regulatory requirement to make access available to all the documents relating to clinical trials, research protocols and the 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 ;**

**Compromise Amendment 9**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**  
Compromise amendment replacing Amendments 119,129-136

**Motion for a resolution**  
**Paragraphs 8 and 9a**

*Motion for a resolution*

8. Considers the conflicts of interest apparent in the case of some experts who advise the European institutions to give rise to suspicions of undue influence and to undermine the overall credibility of the European health agencies and their recommendations; calls in particular for the EMA and ECDC to revise forthwith their current and future expert screening procedures to ensure complete transparency;

*Amendment*

**9. Recognizes that** conflicts of interest of 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 interests must be avoided;**

**9a. Requests that a definition common to**

*all European public health authorities of what constitutes a conflict of interest be adopted;*

Or. en

**Consolidated Amendment 10**  
**Greens/EFA-ALDE-GUE/NGL**  
Compromise amendment replacing Amendments 138-142

**Motion for a resolution**  
**Paragraph 9 and 9b**

*Motion for a resolution*

*Amendment*

*9b. Calls for the declarations of interest of all experts who advise the European public health authorities to be published, including of members of informal groups, and to be checked by the institution which has solicited them;*

*delete*

9. Calls for the publication of the names, roles and potential conflicts of interest of senior officials who are members of informal groups such as the EU's Health Security Committee, the Health Emergency Operational Facility (HEOF) and the 'vaccines' task force;

Or. en

**Consolidated Amendment 11**  
**EPP-S&D-ECR**  
Compromise amendment replacing Amendments 138-142

**Motion for a resolution**  
**Paragraphs 8 and 9**

*Motion for a resolution*

*Amendment*

*9b. Calls for the declarations of interest of all experts who advise the European public health authorities to be published, including of members of informal groups;*



9. Calls for the publication of the names, roles and potential conflicts of interest of senior officials who are members of informal groups such as the EU's Health Security Committee, the Health Emergency Operational Facility (HEOF) and the 'vaccines' task force;

*delete*

Or. en

**Consolidated Amendment 12**  
**Greens/EFA-EPP-S&D-ALDE-GUE/NLG**  
Compromise amendment replacing Amendments 143-148

**Motion for a resolution**  
**Paragraph 10**

*Motion for a resolution*

*Amendment*

10. Calls for full liability for the quality, safety and effectiveness of a medicinal product to rest with the manufacturer;

10. ***Recalls that according to current Union legislation on medicinal products, the 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 by Member States in all contracts for the procurement of vaccines, as an important element to maintain/regain citizens trust in vaccine safety;***

Or. en

**Compromise Amendment 13**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**  
Compromise amendment covering amendments: 75 (second part), 80, 81, 155, 157-160; amendment 82 would be voted as paragraph 2d (new), amendment 83 would be voted as paragraph 2e (new),

**Motion for a resolution**  
**Paragraph 11**

*Motion for a resolution*

*Amendment*

***COOPERATION***

*delete*

11. Demands precise definition of the roles, duties, remits, limits, relations and responsibilities of the Commission, the ECDC, the EMA and the Member States and also of 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;

***2. Requests to clarify and if necessary review, the roles, duties, remits, limits, relations and responsibilities of the key actors and the structures of management of medical threats at the level of the EU which are the European Commission, the ECDC, the EMA and the Member States and also of 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, to make that information publicly available;***

***2a. Emphasises the need to reinforce cooperation between Member States and coordination of Member States with ECDC to ensure coherent risk management in the response to a pandemic in compliance with the International Health Regulation;***

***2b. Considers it advisable to reinforce the mandate of the Committee of Public Health the action and role of which should be improved to better support 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.***

Or. en

**Compromise Amendment 14**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**  
Compromise amendment replacing Amendments 84

**Motion for a resolution**  
**Paragraph 2c (new)**

*Motion for a resolution*

*Amendment*

***2c. Urges the WHO to revise the definition of a pandemic, taking into consideration not only its geographical spread but also its severity;***

**Consolidated Amendment 15**  
**Greens/EFA-EPP-S&D-ALDE-GUE/NLG**

Compromise amendment replacing Amendments 85, 88, 163-168, 170

**Motion for a resolution**  
**Paragraph 12**

*Motion for a resolution*

12. Expresses its approval of the introduction of a procedure enabling the Member States to make group purchases of anti-viral vaccines and medicinal products on a voluntary basis where the positive benefit-risk profile of their preventive/therapeutic effect is clearly demonstrated and indisputable, in order to obtain, for a given product, advantageous rates approaching its cost price;

*Amendment*

3. Expresses its approval of 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*;

**Amendment 16**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**  
Compromise amendment replacing Amendments 171

**Motion for a resolution**  
**Paragraph 13**

*Motion for a resolution*

13. Considers it essential for its Members and the European public to be informed of these revisions and details at the earliest opportunity;

*Amendment*

13. 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 actions that seek to prepare and prevent pandemics*;

**Compromise Amendment 17**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**  
Compromise amendment replacing Amendments 7-11

**Motion for a resolution**  
**Recital A**

*Motion for a resolution*

A. whereas the national and international health authorities, including the WHO, were aware as early as May 2009 that the H1N1 influenza was not virulent, with this moderate virulence being confirmed by the very low mortality rate observed as a result of this influenza ‘pandemic’ in comparison with the officially recognised figures for seasonal influenza,

*Amendment*

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 only be hoped (thus not taken for granted) that this pattern would continue,**

Or. en

**Consolidated Amendment 18**  
**Greens/EFA-EPP-S&D-ALDE-GUE/NLG**  
Compromise amendment replacing Amendments 14-21

**Motion for a resolution**  
**Recital B**

*Motion for a resolution*

B. whereas the criteria for defining a ‘pandemic’, adopted by the WHO in 2009 and based solely on the propagation of the virus while discounting the severity of the infection, distorted the meaning of the word ‘pandemic’ and triggered a false alarm worldwide, with that alarmism giving rise to inappropriate public health decisions and a disproportionate response among the public and administrations of the European Union and its Member States,

*Amendment*

B. whereas the criteria for defining a ‘pandemic’, **as revised** by the WHO in 2009, **are** based solely on the **spread** of the virus while discounting the severity of the **illness caused by it,**

Or. en

**Compromise Amendment 19**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**

Compromise amendment replacing Amendments 28-30, 31 (first part), 32-33

**Motion for a resolution**

**Recital C**

*Motion for a resolution*

C. whereas the exaggerated costs arising from the management of this crisis in the Member States are primarily a direct consequence of the EU's lack of independence and critical acumen in relation to the risk evaluation conducted by the WHO,

*Amendment*

C. 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,***

Or. en

**Compromise Amendment 20**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**

Compromise amendment replacing Amendments 34, 35 and 36

**Motion for a resolution**

**Recital D**

*Motion for a resolution*

D. whereas the expenditure committed by the Member States to the response plans drawn up is mainly in connection with the purchase of vast quantities of vaccines,

*Amendment*

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

Or. en

**Compromise Amendment 21**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**  
Compromise amendment replacing Amendments 40-48

**Motion for a resolution**

**Recital E**

*Motion for a resolution*

E. whereas this systematic vaccination strategy is based essentially on an approach that relies on blind faith in the effectiveness of influenza vaccines, without taking into account scientific data that contradict that belief (see Cochrane journals),

and the majority of the studies available on the efficacy of the medicinal products, including vaccines, have been conducted by pharmaceutical companies, meaning that no objective proof has been provided of the efficacy of influenza vaccines,

*Amendment*

E. 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,***

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

***Eb. 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,***

Or. en

**Compromise Amendment 22**  
**Greens/EFA-EPP-S&D-ALDE-ECR-GUE/NLG**  
Compromise amendment replacing Amendments 52-54

**Motion for a resolution**

**Recital F**

*Motion for a resolution*

F. whereas the differing recommendations made within the EU and Member States on the subject of the priority groups targeted for vaccination illustrate the huge uncertainties surrounding the evaluation of the H1N1 vaccines recommended,

*Amendment*

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

Or. en

**Consolidated Amendment 23**  
**Greens/EFA-EPP-S&D-ALDE-GUE/NLG**  
Compromise amendment replacing Amendments 60-65

**Motion for a resolution**

**Recital I**

*Motion for a resolution*

I. whereas confidence in vaccines against H1N1 influenza was also undermined by the partial transfer from the manufacturer to the Member State, in the purchase contracts, of liability for any side effects,

*Amendment*

I. ***whereas according to the Commission the reluctance of vaccine suppliers of bearing full product liability may have contributed to reduce 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,***

Or. en