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DRAFT 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

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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

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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],

– having regard to the ECDC interim guidance on 'Use of specific pandemic influenza vaccines during the H1N1 2009 pandemic'[4],

– having regard to the WHO guidance document of April 2009 on pandemic influenza preparedness and response[5],

– having regard to the Council Conclusions of 30 April 2009[6] on Influenza A/H1N1 infection,

– having regard to the exchange of views between the ECDC director and its 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[7],

– having regard to the Commission Staff Working Document of 15 September 2009 on Joint procurement of vaccine against influenza A (H1N1)[8],

– having regard to the Commission Staff Working Document of 15 September 2009 on

[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
[4] http://www.ecdc.europa.eu/en/publications/Publications/0908_GUI_Pandemic_Influenza_Vaccines_during_the_H1N1_2009_Pandemic.pdf
[5] http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html
[6] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/107492.pdf
[7] http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/com481_2009_en.pdf
[8] http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/flu_staff1_en.pdf

communicating with the public and the media on Pandemic (H1N1) 2009[1],

– having regard to the Commission Staff Working Document of 15 September 2009 on support to third countries to fight the Influenza A (H1N1)[2],

– having regard to the Commission Staff Working Document of 15 September 2009 on Regulatory process for the authorisation of antiviral medicines and vaccines in the protection against Pandemic Influenza (H1N1) 2009[3],

– having regard to the Commission Staff Working Document of 15 September 2009 on vaccination strategies against pandemic (H1N1) 2009[4],

– having regard to 'European Strategy for Influenza A/H1N1 – Vaccine Benefit-Risk Monitoring' of October 2009[5],

– having regard to the Council Conclusions of 12 October 2009 on the Pandemic (H1N1) 2009 – a strategic approach[6],

– having regard to the Commission Staff Working Document of 23 November 2009 on Health Security in the European Union and Internationally[7],

– having regard to the Assessment Report of 16 April 2010 on EU-Wide Response to the Pandemic (H1N1) 2009[8],

– having regard to the final report of January 2010 on the Evaluation of the European Medicines Agency[9],

– 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[10],

– having regard to the conclusions of the Conference on lessons learned from the A (H1N1) pandemic, 1 and 2 July 2010[11],

– having regard to the report by the French Senate's committee of inquiry into influenza A entitled 'Influenza A (H1N1)v: reflections on the first pandemic of the 21st Century', published on 29 July 2010[12],

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[1] http://ec.europa.eu/health/ph_threats/com/Influenza/docs/flu_staff2_en.pdf
[2] http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/flu_staff3_en.pdf
[3] http://ec.europa.eu/health/ph_threats/com/Influenza/docs/flu_staff4_en.pdf
[4] 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
[5] http://www.ema.europa.eu/docs/en_GB/document_library/Report/2010/01/WC500044933.pdf
[6] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/110500.pdf,
[7] http://ec.europa.eu/health/preparedness_response/docs/commission_staff_healthsecurity_en.pdf
[8] http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/index_en.htm#fragment2
[9] http://ec.europa.eu/health/files/pharmacos/news/emea_final_report_vfrev2.pdf
[10] http://assembly.coe.int/Mainf.asp?link=/Documents/AdoptedText/ta10/ERES1749.htm
[11] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/116478.pdf
[12] http://www.senat.fr/notice-rapport/2009/r09-685-1-notice.html

– having regard to the recommendations of the European Ombudsman concerning the European Medicines Agency of 29 April and 19 May 2010[1],

– having regard to the Assessment Report of 25 August 2010 on EU-Wide Pandemic Vaccine Strategies[2],

– having regard to the Council Conclusions of 13 September 2010 on Lessons learned from the A/H1N1 pandemic – Health security in the EU[3],

– 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 (A7-0000/2010),

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,

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,

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,

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,

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,

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,

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[1] 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

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

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

G. whereas significant changes are required to the current healthcare system in the EU and its Member States in order to achieve general public health objectives, as opposed to a purely pharmacological approach,

H. 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,

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,

J. whereas information has been garnered by various parliamentary committees and evaluation missions conducted in the EU Member States on the action taken to combat H1N1 influenza,

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;

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;

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;

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;

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;

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;

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;

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;

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;

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

COOPERATION

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;

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;

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

14. Instructs its President to forward this resolution to the Council, the Commission 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. It is nevertheless striking to note how low these figures are 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. What is even more astounding is that whether there has been wholesale vaccination or not, such as in Poland, where there was no vaccination at all, the death rates in the European countries affected by this influenza are still comparable. Should one reassess the supposed severity of H1N1 influenza? The answer is surely yes. Moreover, public health now experts agree that H1N1 influenza was of relatively moderate virulence.

It should nevertheless be pointed out that 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. The Member States and European institutions accepted this maximum-level alert, triggering a raft of measures that were costly, pointless and disproportionate to the actual – and known – severity of H1N1 influenza.

The analysis of the management of H1N1 influenza in the European Union thus reveals a striking contrast between the number of deaths associated with H1N1 influenza and the number of deaths associated with seasonal influenza, amounting to a sad but limited loss of life. Then there are the very sizeable costs incurred in the Member States and at EU level as a result of the health measures undertaken. For example, those costs are put at EUR 1 300 million in Great Britain and EUR 990 million in France (as against EUR 87 million in the case of seasonal influenza).

This difference, and this seemingly excessive expenditure has, moreover, formed the subject, within the European Union, of numerous parliamentary inquiries, fact-finding missions and more or less independent evaluations by the health authorities involved. In its resolution of 24 June 2010, the Parliamentary Assembly of the Council of Europe stated that it was 'alarmed about the way in which the H1N1 influenza pandemic has been handled, not only by the World Health Organization (WHO), but also by the competent health authorities both at the level of the European Union and at national level.' It was 'particularly troubled by some of the consequences of decisions taken and advice given leading to the distortion of priorities of public health services across Europe, the waste of large sums of public money and unjustified fears about health risks faced by the European public at large.'

The European Union needs greater independence

The analysis of the management of H1N1 influenza in Europe thus highlights an underlying problem: that of a lack of independent evaluation by our national and/or European health authorities. Indeed, the sets of measures implemented were not proportionate responses formulated on the basis of the scientific information available. On the contrary, the decisions taken amounted to rigid application of measures programmed in advance. 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 three quarters of the Member States, the policies on the purchasing of vaccines were a direct upshot of 'sleeping contracts' signed back in 2007 with pharmaceutical companies. The stock 'pandemic' vaccines given to millions of people in Europe were the subject of extraordinary 'facilitated' authorisation procedures, based in fact on old studies and vaccine formulae produced at the time of the H5N1 virus, which also dated from the years 2005/2007.

These examples illustrate the great lack of suppleness and flexibility of the European institutions, which showed themselves incapable of departing from initial forecasts and adapting, as best as possible and in real time, to the actual clinical and epidemiological statistics available. This formidable lock-step in decision-making, particularly at political level,c goes a long way to explaining the inertia and staggering costs arising from undue and unbridled health alarmism over a supposed influenza 'pandemic' which, in the words of one French expert, looked very much like a 'minor flu outbreak'.

Beyond the responses adopted, the European Union was also 'copy-cat' in its risk evaluation, aligning itself unreservedly with the excessive alarmism issuing from the WHO. This stance led the Member States to implement pre-devised preparedness plans, which included honouring orders for vaccines under sleeping contracts signed with vaccine manufacturers during the previous influenza crisis with H5N1. Those orders came at a high price, along with a liability for side-effects that now rested with the Member States rather than with the pharmaceutical companies. That clause ran counter to standard European practice.

However, it is not obligatory to adhere to the WHO's opinion. In 1986, after the explosion at the Chernobyl nuclear power station, the European Community set foodstuff contamination standards that were far more stringent than those recommended by the WHO (600 becquerels of caesium-137 per kilo of food and 370 Bq for infant foodstuffs, while the WHO recommended 1 000 Bq per kilo).

Are copy-cat and easily-influenced European health institutions what is wanted? Or should they be able to forge their own opinion and disseminate their own expertise without being dependent on other international organisations, accomplishing tasks financed by the European taxpayer? Your rapporteur aimed to provide satisfactory answers to those questions through her proposals, in order to restore the European public's confidence in Europe's health institutions.

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 in particular the systematic use of vaccines. It should be said that the effectiveness of influenza vaccines is hotly disputed in many studies conducted by the Cochrane Foundation and published in leading scientific journals. These doubts increase if one carefully considers the clinical trial protocols developed by vaccine manufacturers to demonstrate the efficacy of their vaccines. 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 conclusions of the conference on the lessons learned from the A(H1N1) pandemic state 'to date we have been too dependent on the pharmaceutical companies for these studies'. When asked to comment on the soundness of the scientific references for 'pandemic' vaccines, Zsuzsanna Jakab, former head of the ECDC, stated that 'no vaccine had ever been authorised on the basis of so little scientific information'.

The European Union needs closer cooperation

The assessment of the management of H1N1 influenza shows that vaccination strategies differed. Some Member States opted for wholesale vaccination, others targeted vaccination, and Poland none at all. That clearly evinces suspicion as regards evaluated vaccine risks.

It is essential that the sovereignty of the national authorities be respected in decisions concerning the use of medicinal products. In the case of vaccines and medicinal products with a clearly-demonstrated favourable benefit-risk profile, it is recommended that Member States band together, on a voluntary basis, to secure advantageous rates in negotiations. This would be in direct application of Article 168(2) of the Treaty on the Functioning of the European Union.