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## Social, Health and Family Affairs Committee

# The handling of the H1N1 pandemic: more transparency needed

Memorandum

Rapporteur: Mr Paul FLYNN, United Kingdom, Socialist

### I. Introduction

1. The Parliamentary Assembly has always attentively observed governance issues of the public health sector in Council of Europe member states. The most recent reporting activities in this respect have been Recommendation 1725 (2005) on “Europe and bird flu – preventive measures in the health field”, Recommendation 1787 (2007) on “The precautionary principle and responsible risk management” and Resolution 1649 (2009) on “Palliative care: a model for innovative health and social policies”.

2. The rapporteur notes that the handling of the current H1N1 crisis is closely related to sensitive questions such as health experts’ contractual relations with private stakeholders and possible conflicts of interest, levels of public spending and, last but not least, important issues of health and well-being of individual patients and the population at large. Furthermore, the transparency of public health decisions is closely linked to the way in which sensitive issues are communicated to the European public. The rapporteur intends to take the ongoing debate on these topical issues to a more objective level.

3. At the level of the Council of Europe, member states undertake intergovernmental co-operation activities regarding health topics with a view to contributing to the development of an ethical European health policy. Some of the main topics include blood transfusion, mental health, palliative care, patient participation transplants, and also good governance in the health sector, as well as bioethics and the quality of medicines and healthcare. For the Council of Europe and its Parliamentary Assembly, the observation of public governance in the health care field is a particular priority.

4. The rapporteur does not wish to undertake a scientific analysis of the H1N1 flu virus, which would be the specific mission of other international or European bodies such as the World Health Organisation (WHO), the European Centre for Disease Prevention and Control (ECDC) or the European Medicines Agency (EMA). His memorandum is based, rather, on the understanding that the questions of public health governance arising from the H1N1 crisis are essential issues of the rule of law and democracy which are ‘core values’ of the Council of Europe. The rapporteur’s main objective therefore is to identify and propose lines of action to enhance the transparency, accountability and coherence of the handling of future public health situations, whether these reach ‘pandemic’ levels or not.

5. With regard to public health issues at the Parliamentary Assembly, the rapporteur notably wishes to refer to the current report of his colleague, Ms Liliane Maury Pasquier (Switzerland, SOC), Chair of the Social, Health and Family Affairs Committee, on “Preventive Health Care Policies in the Council of Europe member states”. In her draft recommendation, Ms Maury Pasquier proposes that the Assembly urges Council of Europe member states to evaluate their preventive health care strategies, to renew their commitment towards the health goals of the World Health Organisation (WHO) and to actively co-operate with WHO, within the global surveillance system, in order to halt the expansion of infectious diseases. Taking this approach into account and despite some of the criticisms raised in this memorandum, the Parliamentary

Assembly should recognise the outstanding achievements made in public health in past decades, and the valuable contribution to this by WHO. The Assembly should continue to support WHO to improve public health in all possible ways, including from a good governance and human rights perspective.

6. When examining the handling of the H1N1 influenza, the rapporteur also considers it important to closely co-operate with WHO and main European bodies, including the European Commission and Parliament, as well as national governments, the pharmaceutical industry, academia and civil society. This dialogue has already been launched at the public hearing held on 26 January during the 2010 first part-session of the Assembly, the results of which have been included in the present memorandum. This dialogue will continue at a hearing in Paris on 29 March 2010, with the participation of public health experts and representatives of European governments.

## **II. Announcement and perception of the H1N1 'Pandemic'**

7. Very rapidly after the detection of the first cases of infection in Mexico in April 2009, the H1N1 virus, occurring world-wide, was declared a pandemic on 11 June 2009. This declaration kicked off an immediate international agenda setting in process extensive vaccination campaigns in many countries notwithstanding evidence that the influenza overall presented relatively mild clinical symptoms. In autumn 2009, several independent medical experts raised warnings regarding excessive vaccination activities for which, according to them, there was no scientific evidence to justify this.

8. According to information provided by WHO infections were reported in 9 countries on 29 April 2009, then cases confirmed in 74 countries and territories on 11 June, and just a few weeks later, on 1 July, there were confirmed infections in 120 countries and territories around the world. According to WHO, it is this global spread which led the Organisation to call for increasing phases of pandemic emergency and to tell the world that a pandemic was definitely under way<sup>1</sup>.

9. From the very beginning of the disease in April 2009, it was clear that a newly combined flu virus was on its way, just as many flu virus variations had in the past been seen on an almost annual basis. From this common perception onwards, the H1N1 influenza was however looked at from different points of view within the medical community. For some experts, it seemed to be evident, from a relatively early stage, that the new sub-type of influenza virus was doing less harm to infected humans than others in former years. For those in favour of far-reaching measures, the approach recommended by WHO and followed in many countries was justified by the 'precautionary principle': numerous scientists had expected the outbreak of a new world-wide pandemic for a long time and were therefore extremely sensitive to the possible dramatic consequences of any new viruses. However, on the 'precautionary principle' followed by WHO and recommended for national action, responses varied: some wished to take strong precautions, whilst others expected a lower level of outbreak of the disease, and took minimal steps. This can be seen from some of the various reactions by member states of the Council of Europe.

10. Even though there is some understanding for 'precautionary approaches' followed in public health questions, the rapporteur – supported by various other members of the Social, Health and Family Affairs Committee at the public hearing on 26 January – raised the question to WHO as to why they had maintained the same precautionary attitude, even when empirical evidence had later shown that the pandemic had been much milder than initially expected. As recent WHO statements indicate (see below), there has been no revision by WHO of its assessment, notwithstanding the actual situation experienced throughout the world. Whilst WHO insists on maintaining the pandemic at level 6 against all evidence, it continues to face increasing doubts and questions as to its credibility by many stakeholders and the European public at large.

## **III. Critical views of the governance of the current H1N1 crisis and first evidence found**

11. Independent experts from the medical community mainly criticised the agenda setting and governance process concerning the H1N1 flu in terms of the criteria used for declaring a pandemic, the lack of empirical evidence justifying such a step and the clearance to use certain medicines and vaccines. They also repeatedly raised the issue of the influence that private stakeholders from the pharmaceutical industry might have had on major decisions taken by international and national authorities. For the purpose of this memorandum the rapporteur has compiled the main issues raised in a critical perspective. All arguments presented seem to have one common reference point: the disparity between the relatively mild unfolding of the influenza and the actions taken at European and national level.<sup>2</sup>

<sup>1</sup> WHO: Transcript of the virtual press conference held on 14 January 2010 with Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza, WHO.

<sup>2</sup> Mainly drawn from allegations presented by various members of the scientific community, quoted from different press

a) *Interpretation of scientific and empirical evidence with a view to declaring a pandemic and deciding on subsequent vaccination strategies*

12. WHO states that worldwide more than 213 countries and overseas territories or communities have reported laboratory confirmed cases of pandemic influenza H1N1 2009, including at least 16 455 deaths.<sup>3</sup> Firm conclusions, however, will only be reached after April 2010, the month when a normal influenza season usually ends. Reliable estimates of the number of deaths and the mortality rate during the current pandemic will only be possible, according to the Organisation, one or two years after the pandemic has ended.<sup>4</sup> According to very recent information from the European Centre for Disease Prevention and Control (ECDC), while symptoms of the disease are mild in most persons, a significant minority of people are suffering severe disease and dying as a result. The majority of people suffering severe disease are those in high risk groups: people with other chronic medical conditions such as asthma or heart disease.<sup>5</sup>

13. When looking at the still very moderate expression of the pandemic almost one year after its outbreak, the way in which scientific and empirical evidence has been interpreted can be seriously questioned. The main question is whether WHO overstated the threat posed by the virus, ignoring the practical evidence that the pandemic seemed to be of “moderate severity” from its very start. With regard to such a possible overstatement, the rapporteur would notably like to point out that, in many countries, no clear distinction had been made between patients dying *with* swine flu (i.e. showing symptoms of swine flu whilst having died of other pathologies) and patients dying *of* swine flu (i.e. swine flu being the main lethal cause).

14. It was notably WHO’s rapid move towards pandemic level 6, at a time when the influenza presented relatively mild symptoms, combined with the change in the definition of pandemic levels just before the declaration of the H1N1 pandemic, which raised the scientific community’s concerns and suspicion. Although WHO continues to assert that the basic definition of a pandemic has never changed, there is watertight evidence that the former criteria of the impact and severity of an epidemic in terms of the number of infections and deaths was not considered anymore in the definition used for entering pandemic level 6, when the new WHO influenza guidance was published in May 2009<sup>6</sup>. As Dr. Wolfgang Wodarg, German epidemiologist and former member of the Parliamentary Assembly – and as such one of the initiators of the present report – recalled during the discussion in January 2010, the current pandemic could only have been launched by changing the definition of a pandemic and by lowering the threshold for its declaration.

15. Beyond the main strands of criticism regarding overstatement and untimely changes of definition, the rapporteur would also like to highlight a question raised by many medical experts during recent debates: Was the development of new vaccines absolutely required for the treatment of the H1N1 influenza? Given that new flu virus variations are detected almost every year, the H1N1 virus could possibly have been treated by flu vaccines in stock, instead of producing a special vaccine, thus speeding up some of the authorisation procedures and creating public health risks.

16. Seemingly, most vaccines used during national vaccination campaigns – such as Pandemrix, Focetria, Celvapan - were authorised according to the formal procedure followed by the European Medicines Agency (EMA) although not all of them were clinically tested on vulnerable persons such as children<sup>7</sup>. In its official statements, the agency asserted that, despite the short delays within which vaccines were authorised, they had been sufficiently tested, including the adjuvant used, some of which remain highly controversial within the medical community<sup>8</sup>. There is, however, evidence that at least one vaccine without adjuvant of Sanofi-Pasteur (Panenza) was treated differently and was able to receive national authorisation in some countries, such as France for example, without passing through some of the rigid European procedures<sup>9</sup>. Without

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articles published between December 2009 and March 2010, as well as from various statements made during the hearing organised at the meeting of the Social, Health and Family Affairs Committee in Strasbourg on 26 January 2010.

<sup>3</sup> WHO: Pandemic (H1N1) 2009 – Weekly update 90, 5 March 2010.

<sup>4</sup> WHO: Progress in public health during the previous decade and major challenges ahead. Dr Margaret Chan, Director-General, Report to the Executive Board at its 126<sup>th</sup> session, Geneva, Switzerland, 18 January 2010.

<sup>5</sup> European Commission / Directorate of Health and Consumers: Pandemic (H1N1) 2009 – Factsheet, March 2010.

<sup>6</sup> WHO: Pandemic influenza preparedness and response: a WHO guidance document, May 2009.

<sup>7</sup> EMA: Pandemic influenza A(H1N1)v vaccines authorised via the core dossier procedure. Explanatory note on scientific considerations regarding the licensing of pandemic A(H1N1)v vaccines. London. 24 September 2009.

<sup>8</sup> The adjuvants are so-called inert products which are added to a vaccine in order to stimulate the immune reaction, by reinforcing the production of antibodies (Prof. Daniel Floret, Technical Director of the High Council of Public Health in France, September 2009)

<sup>9</sup> Stéphane Horel : Les Médicamenteurs – Labos, Médecins, Pouvoirs publics : enquête sur des liaisons dangereuses, Editions du moment, Février 2010.

wishing to take a definitive stance on this highly specific, scientific question here, it seems entirely justified to raise the question whether scientific evidence was sufficient to remove any remaining doubts about the relevant products. Similar concerns were presented – and are also justified from the rapporteur's point of view - regarding some of the anti-flu medication (Tamiflu, Relenza etc.).

*b) Possible influence of the pharmaceutical industry on public health decisions and conflicts of interest of scientific experts involved*

17. For the rapporteur, one of the central issues of the ongoing debate concerns the possibility for representatives of the pharmaceutical industry to directly influence public decisions taken with regard to the H1N1 influenza, and the question of whether some of their statements had been adopted as public health recommendations without being based on sufficient scientific evidence (such as for example, the recommendation on double vaccination)? Various factors have led to the suspicion that there may have been undue influence by the pharmaceutical industry, notably the possibility of conflicts of interest of experts represented in WHO advisory groups, the early stage of preparing contractual arrangements between member states and pharmaceutical companies as well as the actual profits that companies were able to realise as a result of the influenza pandemic.

18. The advisory bodies of WHO are particularly exposed to the risk of conflicts of interest concerning scientific experts. Amongst these bodies are the Strategic Advisory Group of Experts (SAGE) serving as the principal advisory group to WHO for the development of policy related to vaccines and immunisation at a strategic rather than a technical level, and also the Emergency Committee which advises WHO Director-General under the provisions of the revised International Health Regulations (IHR) which have been in force since 2007, notably on matters such as declaring a public health emergency of international concern or the need to raise the level of pandemic alert following the spread of a virus such as H1N1. As a general rule, neither of these committees have any executive or regulatory functions; their members are appointed by WHO Director-General and they have to sign declarations of interest and confidentiality.

19. Some members of these advisory bodies evidently have professional links to certain pharmaceutical groups - notably through receiving extensive research grants from the big pharmaceutical groups - so that the neutrality of their advice could be contested<sup>10</sup>. To date, WHO has failed to provide convincing evidence to counter these allegations and the organisation has not published the relevant declarations of interest taking such a reserved position, the Organisation has joined other bodies, such as the European Medicines Agency (EMA), which likewise, have still not published such documents. The rapporteur is convinced that it is entirely justified to require transparency of the profiles of experts whose recommendations have far-reaching consequences for the public health sector. However, even at the public hearing held in Strasbourg in January 2010, WHO continued to hold back on releasing further information on the interests of experts, using the justification of the need to protect their 'privacy'.

20. Another factor which nurtured suspicions about undue influence was the fact that the pharmaceutical companies had a strong vested interest in the declaration of a pandemic and subsequent vaccination campaigns. This interest arose from recent contractual arrangements regarding any new influenza pandemic (some were concluded between member states and pharmaceutical groups in the period 2006/2007 just after the avian flu scare). Various European countries signed so-called "sleeping" contracts with large pharmaceutical groups which were supposed to take effect on the declaration of a pandemic by WHO.

21. The commercial interests in the pandemic and vaccination campaigns can be illustrated by the high levels of benefit to pharmaceutical companies. According to estimations by the international investment bank JP Morgan, the sales of H1N1 vaccines in 2009 were expected to result in overall profits of between 7 and 10 billion dollars to pharmaceutical laboratories producing vaccines. According to figures presented by Sanofi-Aventis at the beginning of 2010, the group registered net profits of 7.8 billion Euros (+11%) due to a "record year" of anti-flu vaccines sales<sup>11</sup>.

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<sup>10</sup> Stéphane Horel : Les Médicamenteurs – Labos, Médecins, Pouvoirs publics : enquête sur des liaisons dangereuses, Editions du moment, Février 2010.

<sup>11</sup> Agence France Presse (AFP) on 9 February 2010.

c) *Handling of the pandemic situation by member states*

22. Member states have to ask themselves a complex set of questions: Was the actual handling of the H1N1 influenza and the declaration of a pandemic, including subsequent vaccination activities, not an irresponsible way of dealing with public health budgets? Did member states' health authorities deploy all means required for taking objective and well-founded decisions in this situation? What were the national mechanisms to ensure that recommendations of WHO were implemented in a transparent manner? What were member states' chances to 'opt out' of the recommendations and follow their own lines of action (as apparently already done on previous occasions)? Did the perception of risk by WHO justify some of the extreme warnings regarding the high numbers of deaths anticipated? Why did the predictions relating to the incidence of H1N1 flu cases vary so much between different countries in Europe?

23. These issues show that member states are both at the 'receiving end' of advice coming from WHO and other international bodies, and key players, when it comes to national pandemic preparedness strategies. In this context, two important questions need to be posed. Firstly, were member states well advised regarding pandemic preparedness strategies to be followed and secondly, did member states act in a responsible manner with a view to their citizen's health and well-being. The rapporteur notes that, in some member states, the 'precautionary' approaches followed created a high degree of uncertainty and fear amongst the population, which were not necessarily justified by the evolution of the disease.

24. Some of the questions raised regarding national situations still need to be examined in depth. The rapporteur can only look at a few examples here (see also reference to member states' reactions below). The rapporteur certainly does not intend to judge, on behalf of all Council of Europe member states concerned, if the situation was dealt with appropriately or not. It will also be up to each member state to address the questions he has highlighted and draw their own conclusions.

d) *Communication of sensitive issues in the ongoing debate*

25. The rapporteur is aware of the fact that some of the allegations raised by experts in the European press are far-reaching. He nevertheless considers it as important to openly raise the main critical issues in order to present a full picture and allow all stakeholders involved to respond to the allegations and criticisms made. One of the functions of the Parliamentary Assembly in such a debate is to provide a parliamentary and thus a democratic platform for the discussion of sensitive issues. The rapporteur very much welcomes the fact that some of the stakeholders involved have seized this opportunity and actively participated in the debate organised at the level of the Council of Europe.

26. The hearing organised in January was intended to offer an objective platform for debating a sensitive issue in a context generally characterised by a somewhat emotional debate. Professor Keil, epidemiologist and Director of WHO Collaborating Centre on epidemiology of the University of Münster (Germany), criticised the link and references made to previous deadly influenza pandemics. In his view, the comparison with the 'Spanish flu' of 1918 was generally inappropriate given that empirical figures were far from comparable. The 'Spanish flu' took place in the historical context of World War One where infections were easily transmitted by soldiers, many of whom were undernourished and without medication considered as basic today, such as penicillin. Such comparisons therefore tended to heighten fear amongst Europeans.

27. The January hearing provided a good exchange of views, the opportunity of opening up some of the most sensitive issues or explaining some of the problems that had not yet been communicated in a sufficiently clear manner. One of these aspects was the highly sensitive issue of conflicts of interest of scientific experts, which was mentioned earlier, and the need for transparency, balanced with the respect for privacy of the experts concerned. At this point, the rapporteur would like to raise the question whether, in a situation characterised by a high degree of uncertainty and decreasing confidence in public health decisions following the H1N1 pandemic, the privacy of experts should prevail over the right of 800 million citizens to be openly and fully informed about major decisions that might have an impact on their individual health and well-being?

28. The presentations given by representatives of WHO and the pharmaceutical industry at this public hearing disappointed many European parliamentarians, representing the national parliaments of 47 member states, most of which are also members of WHO. The rapporteur therefore hopes that some of the remaining sensitive issues will be addressed in more detail at the forthcoming exchange in Paris in March.

#### IV. Recent reactions of various stakeholders involved in the handling of the H1N1 influenza

##### a) *Reactions of WHO at different times of the pandemic*

29. Since the beginning of the threat posed by H1N1, national, European and international health officials have vigorously denied the allegation that there was a lack of scientific evidence to justify the action taken and that there was a lack of transparency regarding the decision-making processes relating to the declaration of a pandemic. In statements made at the very beginning of 2010, WHO insisted that the world was facing a real pandemic, the future course of the pandemic was uncertain, the situation was neither overplayed nor underplayed, and that the objective had always been to adopt a precautionary approach. In the same statements, WHO claimed that it was too early to say whether the pandemic was over and that another significant wave could still be expected across Europe this winter or spring.

30. At the hearing in January 2010, Mr Keiji Fukuda, Special Advisor on Pandemic Influenza to the Director General, conceded on behalf of WHO that, during a public health emergency, health officials must sometimes make urgent, often far-reaching decisions in an atmosphere of considerable scientific uncertainty. He remained convinced that it was preferable to see a moderate pandemic with ample supplies of vaccine rather than a severe pandemic with inadequate supplies of vaccine. This justified the action followed in relation to the H1N1 virus. On the same occasion he claimed, on behalf of WHO, that the basic definition of pandemics had never changed. He stated however that the international guidelines used for declaring and responding to a pandemic were updated and made more specific for the sake of clarity.

31. In their statements, WHO also affirmed that the scientific advice received was not influenced by private stakeholders from the pharmaceutical industry and their vested interests. The organisation admitted that, when reaching out to a broad group of experts and interest groups, there was always a potential risk of conflicts of interest in the advice given. It was however common for the Organisation to work with experts who receive research grants in association with industry, but possible conflicts of interest were countered by a number of routine safeguards. According to WHO, transparency is notably ensured by declarations of interest requiring that external experts present all their professional and financial interests, including funding received from pharmaceutical companies, consultancies or other forms of involvement in relevant commercial activities.

32. Nevertheless, WHO has acknowledged in a recent statement that: "Adjusting public perceptions to suit a far less lethal virus has been problematic. Given the discrepancy between what was expected and what has happened, a search for ulterior motives on the part of WHO and its scientific advisors is understandable though without justification"<sup>12</sup>. WHO has stated that it considers existing mechanisms to be satisfactory, but has declared its intention to respond to allegations of undeclared conflicts of interest, which it takes very seriously. Furthermore it has decided to conduct a review of the way in which the ongoing pandemic was handled and to evaluate, notably, its own performance in this situation with the participation of external experts and in reflection of the existing International Health Regulations (IHR).<sup>13</sup>

33. The rapporteur very much welcomes WHO's readiness to enter into an open dialogue with national parliamentarians from the Council of Europe. He recalls that the initiative taken by the Assembly should not be seen as accusations by one international organisation to another. The debate should rather be perceived as one between member states whose interests are represented by different institutions in a complementary manner. The almost identical geographical coverage of WHO in Europe and Council of Europe member states should facilitate such a dialogue. In this context, the rapporteur remains aware of the reservations that some fellow parliamentarians have with regard to the current debate. For example at the hearing in January, Ms Roseira (Portugal, SOC), member of the Social, Health and Family Affairs Committee and former Minister of Health of Portugal, considered that allegations should not be made against WHO without objective proof. Moreover, the rapporteur remains convinced that allegation of lack of transparency and other problematic issues identified in the handling of the H1N1 need to be unveiled by the various stakeholders through an open dialogue and a cooperative approach.

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<sup>12</sup> WHO: Pandemic (H1N1) 2009 briefing note 19, 3 December 2009, Geneva.

<sup>13</sup> WHO: Transcript of the virtual press conference held on 14 January 2010 with Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza, WHO.

*b) Reactions of the pharmaceutical industry*

34. The rapporteur also takes note of some of the reactions coming from the pharmaceutical industry. Realising that the H1N1 influenza was much milder than originally expected or feared, the pharmaceutical groups allowed many states to opt out of previous contractual arrangements and cancel orders for large quantities of non-delivered vaccines. The rapporteur also welcomes the readiness of the pharmaceutical industry to participate in the open dialogue launched by the Parliamentary Assembly in order to clarify the situation and respond to allegations of undue influence on WHO's decisions.

35. According to the pharmaceutical industry itself, the need for action generated by the declaration of the pandemic in summer 2009, demanded an unprecedented level of collaboration, involving WHO, national governments, health authorities, regulatory agencies, scientists, healthcare professionals and private sector companies, in order to deliver the appropriate countermeasures.<sup>14</sup> However, during the first exchange at the January hearing, the representative of the pharmaceutical industry did not provide any new evidence to dispel doubts about the possible influence that some of their members might have had on public health decisions.

*c) Follow-up and reactions at the level of the European Union and European Parliament*

36. The European Union closely followed and continues to follow the H1N1 pandemic through the European Centre for Disease Control and Prevention (ECDC). This European Agency even provided daily updates on the situation. The most recent figures presented by them were totally in line with whose statistics previously quoted. However, although they also considered that the pandemic was far from over and that considerable uncertainties remained, the ECDC Public Health Event Strategy Team (PST) decided to downgrade their crisis management activities in January 2010, thus stopping the publication of the daily updates. After this date, the ECDC has nevertheless continued its work under a reinforced general influenza programme<sup>15</sup>.

37. Both the European Commission and the European Parliament are currently investigating the handling of the H1N1 influenza within their institutions and agencies. At the European Commission, an investigation on how the H1N1 pandemic was managed by EU Member States and the Institutions is underway. This will lead to a planned Belgian Presidency and European Commission conference at the beginning of July 2010. Furthermore, the European Commission announced on 9 March 2010, the launch of new research projects on influenza. Four collaborative research projects have been shortlisted for funding. They involve 52 research institutes and small and medium enterprises (SME) from 18 European countries and 3 international partners (Israel, China and the United States). This brings the total Commission funding in this field to over €100 million since 2001. Finally, an initiative to set up an investigation committee was launched within the European Parliament by Michele Rivasi member of the Group of Greens/European Free Alliance. She is optimistic that she will collect the required 183 signatures amongst MEPS by April 2010.

*d) Various reactions in Council of Europe member states*

38. Just as different members of the medical community are divided in their positions, Council of Europe member states showed diverse reactions to the H1N1 pandemic. Some showed very reserved attitudes and low-profile vaccination campaigns (Poland). Others adopted highly pro-active approaches to pandemic preparedness (UK, France) and some countries carried out uncontested vaccination campaigns for a greater part of the population (Finland).

39. In the United Kingdom, the Department of Health initially announced that around 65 000 deaths were to be expected. In the meantime, by the start of 2010, this estimate was downgraded to only 1 000 fatalities. By January 2010, fewer than 5 000 persons had been registered as having caught the disease and about 360 deaths had been noted. In March 2010, the rapporteur had the occasion to meet with Gillian Merron, Minister of State for Public Health, in order to discuss the handling of the H1N1 influenza at national level, and was informed that an independent internal investigation by the Cabinet Office was underway, the results of which would be reported after June 2010.

<sup>14</sup> European Vaccine Manufacturers (EVM) statement on Council of Europe debate on 'Faked Pandemics – a threat for health', edited on 14 January 2010, Brussels.

<sup>15</sup> European Centre for Disease Control and Prevention (ECDC): ECDC Daily Update on the 2009 influenza A(H1N1) pandemic, 19 January 2010.

40. In the case of France, some of the main issues raised in the present memorandum, have already been addressed at a national level. Critical observers of the pandemic also openly questioned the neutrality of “independent experts” being represented in some of the official national bodies, such as the Committee for fighting the influenza (“Comité de lutte contre la grippe”)<sup>16</sup> The National Assembly and Senate have taken a proactive approach and have organised a public hearing on the possible action by researchers and public authorities with regard to the H1N1 influenza through the Parliamentary office for the evaluation of scientific and technological choices<sup>17</sup>. The French Senate also launched an inquiry committee on the role of pharmaceutical companies in the handling of the H1N1 influenza by the French government, which started its investigations in February 2010 with a view to presenting a report in August 2010.

41. Some of the figures available for France illustrate very well the extent to which the H1N1 pandemic might have been overstated and the consequences for public health budgets: In France, 263 persons had died of influenza by 21 January 2010, according to the National institute for the monitoring of health issues (“Institut national de veille sanitaire”). By contrast, seasonal influenza generally causes between 4 000 and 6 000 deaths. In the light of the actual development of the H1N1 crisis, the French government managed to cancel orders for 50 million doses of vaccine, whilst 94 million were initially ordered. Vaccines have been sold on to some other countries, but France has been left with millions of unnecessary doses as ‘only’ five million people were vaccinated prior to the start of 2010. These figures are given as one among many examples for countries across Europe<sup>18</sup>.

42. Certain member states did not rush into taking action following the announcement of the pandemic. Poland, for example is one of the few countries worldwide not to have purchased large quantities of vaccines over safety fears and distrust in the pharmaceutical companies producing them. The rapporteur is currently undertaking further research in order to present more specific information on the way in which the pandemic was handled in various countries. The second expert hearing in Paris on 29 March 2010 will include a number of representatives of national governments who will be able to contribute to the debate by conveying their specific national experience.

43. Meanwhile, and following criticism of the handling of the H1N1 crisis, some member states have de-intensified their vaccination campaigns showing a certain level of autonomy with regard to continuing pandemic warnings. Many countries are currently attempting to offload the vaccines already purchased but not used, either by opting out of arrangements with pharmaceutical companies, or by re-selling part of their stocks of vaccines to third parties in order to limit the impact on public health budgets very much under strain during the economic crisis.

## V. Conclusions

44. The recent debate on H1N1, notably at a European level, has shown that the situation relating to this influenza is characterised by a high degree of uncertainty. The rapporteur is convinced that the way in which the H1N1 crisis has been handled is lacking in transparency. Certain facts have never been communicated to the European public; others have not been presented clearly enough. Even in this advanced stage of debate, and notwithstanding the lack of transparency has been pointed out on various occasions, some stakeholders are still not ready to react fully to allegations made and make all possible information available.

45. Concluding this first round of reflection on the way in which the H1N1 pandemic was handled, the rapporteur notes that WHO and other public health institutions involved in public decisions on the pandemic, have ‘gambled away’ some of the confidence that the European public has in these highly reputed organisations. This decline in confidence could be risky in the future. When the next pandemic arises many persons may not give full credibility to recommendations put forward by WHO and other bodies. They may refuse to be vaccinated and may put their own health and lives at risk.

46. The rapporteur considers that any further investigation should focus on the question of how to strengthen and render irreproachable the surveillance mechanisms in place within and around WHO. It is essential in this respect to ensure the Organisation’s democratic accountability and transparency of decision-making in relation to its work, and finally to re-increase public confidence in WHO’s recommendations. There are important lessons to be learned for the future from the current H1N1 pandemic and the way in which it has been dealt with.

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<sup>16</sup> Stéphane Horel : Les Médicamenteurs – Labos, Médecins, Pouvoirs publics : enquête sur des liaisons dangereuses, Editions du moment, Février 2010.

<sup>17</sup> Office parlementaire d’évaluation des choix scientifiques et technologiques (OPECST), Assemblée nationale, Paris : Audition publique du 1 décembre 2009 – « Face à la grippe A(H1N1) et la mutation des virus, que peuvent faire chercheurs et pouvoirs publics ? »

<sup>18</sup> Idem to footnote 15 and Reuters on 25 February 2010.

47. The search for improvements should firstly be undertaken through inter-organisational dialogues at national, European and international level. In this respect, the rapporteur welcomes the willingness of WHO and other organisations to participate in the public hearings and debates organised by the Parliamentary Assembly, and hopes that they will continue this dialogue with a view to pursuing the common objective of preparing for future public health situations where the same issues, including those of transparency, might be raised.

48. In parallel, national public health authorities of Council of Europe member states should also contribute to rendering public health decisions more transparent and accountable. This they should do by addressing some of these highly sensitive issues at national level, and by participating in relevant exchanges at the European level. One of the issues to be examined is the democratic control of international organisations such as WHO through relevant bodies (World Health Assembly, Regional Committees of WHO, etc.).

49. There are numerous organisations and institutions at international, European and national level which have been concerned by pandemic preparedness planning and the implementation of subsequent vaccination strategies. Amongst these, the Parliamentary Assembly provides a European platform where issues relating to human rights, the rule of law and democracy can be raised. In this function, the Parliamentary Assembly could remain a moderator and partner in debates. Beyond consideration of sensitive issues related to the current H1N1 crisis, and in consideration of the vast amount of work on common topics which are already the subject of exchanges between WHO and the Council of Europe, the Parliamentary Assembly could even provide a parliamentary forum for regular debates on the activities of WHO. By comparison, there is a yearly institutional dialogue between the Assembly and the Organisation for the Economic Co-operation and Development (OECD). Similarly there are regular reports of the Assembly on the activities of the United Nations High Commissioner for Refugees (UNHCR) and on the International Organization for Migration.