Parliamentary Assembly
Assemblée parlementaire
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COUNCIL OF EUROPE CONSEIL DE L'EUROPE

PROVISIONAL VERSION

The handling of the H1N1 pandemic: more transparency needed

Report
Social Health and Family Affairs Committee
Rapporteur: Mr Paul FLYNN, United Kingdom, SOC

A. Draft resolution

1. The Parliamentary Assembly is 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 at the level of the European Union and at national level. It is particularly troubled by some of the consequences of decisions taken and advice given leading to distortion of priorities of public health services across Europe, waste of large sums of public money, and also unjustified scares and fears about health risks faced by the European public at large.

2. The Assembly notes that grave shortcomings have been identified regarding the transparency of decision-making processes relating to the pandemic which have generated concerns about the possible influence of the pharmaceutical industry on some of the major decisions relating to the pandemic. The Assembly fears that this lack of transparency and accountability will result in a plummet in confidence in the advice given by major public health institutions. This may prove disastrous in the case of the next disease of pandemic scope - which may turn out to be much more severe than the H1N1 pandemic.

3. The Assembly recalls its previous work on good governance in the public health sector in Council of Europe member states, in particular Recommendation 1725 (2005) on “Europe and bird flu – preventive measures in the health field” and Recommendation 1787 (2007) on “The precautionary principle and responsible risk management”. In Recommendation 1908 (2010) on “Lobbying in a democratic society (European Code of conduct on lobbying)”, the Assembly noted that unregulated or secret lobbying may be a danger and can undermine democratic principles and good governance.

4. On a positive note, the Assembly welcomes the review and evaluation processes regarding the handling of the H1N1 pandemic recently launched or about to be launched by WHO, European institutions dealing with health issues and a number of national governments and parliaments. The Assembly urges all parties concerned to continue and reinforce dialogue between public health institutions at all levels and hold more regular exchanges on good governance in the health sector in the future.

5. Notwithstanding the willingness of WHO and the European health institutions concerned to enter into a dialogue and conduct a review of the handling of the pandemic, the Assembly seriously regrets that they have not been willing to share some essential information, in particular to publish the names and declarations of interest of the members of the Emergency Committee of WHO and relevant European advisory bodies directly involved in recommendations concerning the handling of the pandemic. Furthermore the Assembly regrets that WHO has not moved swiftly to revise or re-evaluate its position on the pandemic and the real health risks involved, despite the overwhelming evidence that the seriousness of the pandemic was vastly overrated by WHO at the outset. In addition the Assembly regrets the highly defensive stance taken by WHO, whether in terms of being unwilling to accept that a change in definition of a pandemic was made, or an unwillingness to revise its prognosis on the pandemic.

6. In the light of the widespread concerns raised over the handling of the H1N1 pandemic, the Assembly calls on public health authorities at international, European and national level – and notably WHO– to address in a transparent manner the criticisms and disquiet raised in the course of the H1N1 pandemic, by:

6.1. reviewing the terms of reference of their general governance bodies and special advisory bodies wherever appropriate with a view to ensuring utmost transparency and the highest level of democratic accountability regarding public health decisions;

6.2. agreeing in a transparent manner on a common set of definitions and descriptions concerning influenza pandemics, involving a cross section of expertise, in order to generate a coherent world-wide understanding of such events;

6.3. revising and updating existing guidelines on working with the private sector, or preparing such guidelines where they are lacking, in order to ensure that:

6.3.1. a wide range of expertise and opinions are taken into account, including contrary views of individual experts and opinions of non-governmental organisations;
6.3.2. declarations of interest of experts involved are made public without exception;
6.3.3. collaborating external organisations are obliged to indicate their link with key opinion leaders or other experts possibly subject to conflicts of interest;
6.3.4. all persons subject to conflicts of interest are excluded from sensitive decision-making processes;

6.4. revising communication strategies related to public health matters by taking into account the current social context marked by a high level of access to new technologies and by closely collaborating with the media in order to avoid sensationalism and scaremongering in the public health domain;

6.5. refining and preparing the grounds for the proper use of the precautionary principle in health matters in the future, including through the preparation of fully transparent communication strategies and accompanying education and training measures;

6.6. sharing the results of H1N1 pandemic review processes in the most transparent and comprehensive manner possible amongst all stakeholders concerned, including WHO, European institutions (European Union and Council of Europe), national governments and parliaments, non-governmental organisations and the European public at large, in order to learn from experience, ensure that responsibility is taken for any errors made, and re-establish public confidence in public health decisions and advice;

7. The Assembly furthermore invites WHO, and possibly European health institutions concerned, to engage in more regular European exchanges on the issue of good governance in the health sector by:

7.1 participating in more regular debates on topics related to good governance in the health sector within the Parliamentary Assembly;

7.2. actively contributing to the intergovernmental work undertaken at Council of Europe level on good governance in the public health sector.

8. The Assembly also calls on member states to:

8.1. make use of their means of democratic control through the internal governance systems of WHO and European institutions, with a view to ensuring that this resolution is properly implemented;

8.2. launch critical review processes at national level if they have not yet done so;

8.3. develop systems of safeguards against undue influence by vested interests if they have not yet done so;

8.4. ensure stable funding for WHO;

8.5. consider establishing a public fund to support independent research, trials and expert advice, possibly financed by an obligatory contribution of the pharmaceutical industry;

8.4. ensure that the private sector does not gain undue profit from public health scares and that they are not allowed to absolve themselves of liabilities with a view to privatising profits whilst communitising risks. In order to avoid this, member states should be ready to develop and implement clear national guidelines for dealing with the private sector and to co-operate with one another in negotiations with international corporations whenever necessary.

9. The Assembly invites national parliaments to support national policies aimed at the improvement of governance systems in the public health sector and ensure that they are involved in relevant national review and policy-making processes in order to guarantee the highest democratic accountability possible.

10. Finally, the Assembly invites the pharmaceutical industry, including corporations and associations, to revise their own rules and functioning regarding co-operation with the public sector in order to ensure the highest degree of transparency and corporate social responsibility when it comes to major public health matters.

B. Draft recommendation

1. Referring to its Resolution … (2010) on "The handling of the H1N1 pandemic: more transparency needed", the Parliamentary Assembly notes that there is an urgent need for a thorough review of recent decisions taken by public health authorities at international, European and national level in the framework of the H1N1 pandemic given that a lack of transparency in public decisions undermines democratic principles and good governance.

2. At a time when the current H1N1 pandemic is reaching its final phase, notably in Europe, and when internal review processes of its handling have just begun within WHO, European institutions and national governments, the Parliamentary Assembly urges all authorities involved to recognise the shortcomings identified by the Assembly and implement the measures recommended in Resolution … (2010).

3. The Assembly considers that only a comprehensive and transparent review of decisions and decision-making processes related to the H1N1 pandemic and the subsequent reorientation of public health policies and governance systems will ensure that public confidence in major public health institutions is rebuilt and that national governments and European citizens will follow their advice in future situations involving substantial risks to public health.

4. The Parliamentary Assembly considers that the issue of good governance in the health sector should be one of the priorities of the intergovernmental activities at the Council of Europe given the importance of democratic accountability and transparency in public health decision-making. The Assembly therefore welcomes the recent adoption of Recommendation CM/Rec(2010)6 of the Committee of Ministers to member states on good governance in health systems and the follow-up activities planned with a view to its implementation. It supports the setting up of an expert committee under the European Health Committee (CDSP), to evaluate and monitor the implementation of CM/Rec(2010)6.

5. The Assembly moreover calls on the Committee of Ministers to

5.1. instruct the European Health Committee (CDSP) and related bodies to:

5.1.1. take into account Res… (2010) of the Parliamentary Assembly when it comes to defining the work programme and the indicators to be followed in monitoring processes related to good governance in the public health sector;

5.1.2. not only "monitor and evaluate", but also promote good governance of health systems in all Council of Europe member states through appropriate complementary working methods such as assistance programmes or best practice exchanges wherever considered useful;

5.1.3. launch a parallel work process towards the preparation of a Council of Europe Code of Good Governance taking into account the threats to good and democratic governance identified during the H1N1 crisis, as well as the lessons learned from it;

5.2. encourage member states to actively participate in these Council of Europe activities and promote CM/Rec(2010)6 with a view to its rapid implementation at national level and its consideration when it comes to national review processes concerning the H1N1 pandemic;

5.3. closely observe future debates to be held on good governance in the health sector within the Parliamentary Assembly and take into consideration the outcomes of such debates for the future orientation of the intergovernmental work at Council of Europe level.

C. Explanatory memorandum by Mr Flynn, rapporteur

"The United Nations and business need each other. We need your innovation, your initiative, your technological prowess. But business also needs the United Nations. In a very real sense, the work of the United Nations can be viewed as seeking to create the ideal enabling environment within which business can thrive."

United Nations Secretary-General Ban Ki-moon[1]

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We are supposed to be prepared for a pandemic of some kind of influenza because the flu watchers, the people who make a living out of studying the virus and who need to attract continued grant funding to keep studying it, must persuade the funding agencies of the urgency of fighting a coming plague".

Professor Philip Alcabes in "Dread" [2]

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I. Introduction

1. The Parliamentary Assembly pays particular attention to governance issues in the public health sector in Council of Europe member states. Recent activities of relevance 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 Recommendation 1908 (2010) on "Lobbying in a democratic society (European Code of conduct on lobbying)".

2. In December 2009, a motion was tabled under the title "Faked Pandemics - a threat for health" by Dr Wolfgang Wodarg (Germany, SOC), outgoing member of the Parliamentary Assembly and medical expert specialising in epidemiology. The Social, Health and Family Affairs Committee was mandated by the Assembly to prepare a report and appointed Paul Flynn (UK, SOC) as its rapporteur. At this time, the H1N1 pandemic had already been treated as a major public health issue for more than half a year by most Council of Europe member states after having been officially declared by the World Health Organisation (WHO).

3. The rapporteur is greatly concerned by the handling of the H1N1 influenza pandemic, the decisions taken by the World Health Organization and competent authorities at European level and the advice given to the 47 member states of the Council of Europe. He is particularly alarmed by some of the excessive

[1] The United Nations and the Private Sector – A framework for Collaboration. Global Compact Office, United Nations, September 2008.
[2] Philip Alcabes, Professor of Urban Public Heath at Hunter College's School of Health Sciences and in the Public Health program at the Doctoral School, City University of New York: "Dread - How Fear and Fantasy have Fuelled Epidemics from the Black Death to the Avian Flu". Public Affairs 2009.

responses given to what turned out to be an influenza of moderate severity, and also the lack of transparency of relevant decision-making processes and the possible undue influence of pharmaceutical groups on central decisions. Furthermore he is concerned by the way in which some of the sensitive issues were communicated by public authorities and subsequently picked up by the European media, reinforcing fears amongst the population which sometimes made objective analysis difficult. The aim of this report is to make the ongoing debate on the pandemic more objective at a European level and to identify shortcomings and lessons learned from the H1N1 crisis, not least in the hope of rebuilding public confidence in health decisions which have been taken by WHO and by European and national authorities.

4. The rapporteur welcomes WHO's readiness to enter into an open dialogue with national parliamentarians represented at the Council of Europe Parliamentary Assembly. He recognises the outstanding achievements made in public health in recent decades and the essential contribution of WHO to these. However, it is regrettable that the WHO has not been willing to share some essential information with the Assembly regarding, in particular, membership of and possible conflicts of interest of experts on a key advisory body within WHO.

5. When it comes to examining the handling of the H1N1 influenza and drawing relevant conclusions, the rapporteur assigns utmost importance to the close cooperation between all stakeholders involved. These include, in addition to the Council of Europe and its Parliamentary Assembly, WHO and competent bodies of the European Union, as well as national governments, the pharmaceutical industry, academia and civil society. A broad and open dialogue was held at two public hearings held on 26 January and 29 March 2010 and through a visit by the rapporteur and the Chair of the Social, Health and Family Affairs Committee to WHO's headquarters in Geneva on 15 April 2010[3].

II. Global response to the H1N1 pandemic – basic facts and perception

Declaration of a pandemic

6. WHO describes the H1N1 virus as an influenza virus that had never been identified as a cause of infections in people before the current pandemic. Genetic analyses of this virus have shown that it originated from animal influenza viruses (which explains its common denomination as "swine flu") and is unrelated to the human seasonal H1N1 viruses that have been in general circulation since 1977. There seems to be evidence that antibodies to the seasonal H1N1 virus do not protect against the pandemic H1N1 virus. However, other studies have shown that a significant percentage of the population aged 65 and older do have some immunity against the pandemic virus. This suggests that some persons may have had some cross protection from exposure to viruses that have circulated in the more distant past. Unlike typical seasonal flu patterns in the northern hemisphere, the new virus caused high levels of summer infections. Subsequently infections reached even higher levels of activity during cooler months.

7. During the initial phases of the H1N1 influenza, infections were reported in 9 countries on 29 April 2009, then cases were 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. It was this global spread which led WHO to declare increasing phases of pandemic emergency and inform the world that a pandemic was definitely under way[4]. On 11 June 2009, the pandemic was thus officially declared by designating the situation as pandemic influenza phase 6[5]. This declaration at a very early stage of the event and shortly after the detection of first infections in Mexico in April 2009 was, according to some experts, only possible because the description of pandemic alert phases was modified by WHO in May 2009, and notably the criteria relating to the severity of the disease removed as a pre-condition for passing on to the highest alert level[6].

Numbers of infections and deaths

8. As of May 2010, most countries in the world had confirmed infections of the virus. As of 25 April 2010, more than 214 countries and overseas territories or communities worldwide had reported laboratory

[3] See also the written replies provided by WHO on 17 May 2010 as appended to this report.
[4] 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.
[5] According to WHO: Pandemic influenza preparedness and response: a WHO guidance document, May 2009, pandemic phases 5 and 6 are jointly worded as follows: Phase 5: The same identified virus has caused sustained community level outbreaks in two or more countries in one WHO region. Phase 6: In addition to the criteria defined in Phase 5, the same virus has caused sustained community level outbreaks in at least one other country in another WHO region.
[6] WHO contests that the severity of the disease was ever a pre-condition for pandemic influenza phase 6, see Appendix.

confirmed cases of pandemic influenza H1N1, including over 17 919 deaths. WHO continues to actively monitor the progress of the pandemic through frequent consultations with WHO Regional Offices and member states[7]. Firm conclusions on the outbreak of the pandemic were to be reached after April 2010, the month when a normal influenza season usually ends, however these have not as yet been published by WHO. Reliable estimates of the number of deaths and the mortality rate during the current pandemic will only be possible, according to WHO, one or two years after the pandemic has ended[8]. At the time of preparation of this report, rates of influenza in Europe had gone down and the pandemic virus was only being detected sporadically. The Global Influenza Surveillance Network (GISN) continues monitoring the global circulation of influenza viruses, including pandemic, seasonal and other influenza viruses infecting, or with the potential to infect, humans.[9]

9. Beyond mere numbers of infections, the new virus apparently led to patterns of death and illness not normally seen in seasonal influenza infections. Most of the deaths caused by the pandemic influenza seemed to have occurred among younger people, including those who were otherwise healthy. Pregnant women, younger children and people of any age with certain chronic lung or other medical conditions appeared to be at higher risk of more complicated or severe illness. According to recent information from the European Centre for Disease Prevention and Control (ECDC), while symptoms of the disease were mild in most people, only a significant minority of people suffered severe disease and died as a result.[10]

Vaccination strategies

10. The declaration of a new pandemic caused by the H1N1 virus and the designation of pandemic phase 6 initiated an immediate international agenda setting process and the implementation of vaccination strategies at national level. National regulatory authorities generally licensed or approved vaccines developed by various vaccine manufacturers according to relevant national procedures, sometimes following accelerated procedures in order to make relevant vaccines available more rapidly. WHO was involved from the very start in the vaccination process by mobilising global resources and coordinating the distribution of donated pandemic influenza vaccine to eligible countries in order to help them protect people from developing the H1N1 infection[11].

11. National reactions to the declaration differed widely. Some of the vaccination campaigns run at national level were extensive, others were minimal. Several European countries had already prepared the ground for a pandemic and had prepared so-called “sleeping contracts” with pharmaceutical groups which were to take effect on the declaration of a pandemic by WHO[12]. Some countries followed recommendations by pharmaceutical groups that the vaccination should be given twice in order to ensure full protection against the virus and had therefore purchased corresponding quantities of vaccines. Some of the far-reaching approaches followed were justified by ‘pessimistic’ predictions of numbers of infections and deaths to be expected as a result of the pandemic.

Differing perceptions

12. 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. However, from this common perception, the H1N1 influenza was looked at from different perspectives by member states’ governments as well as within the medical community. Already in summer 2009, some independent medical experts raised warnings regarding the overestimation of the current influenza pandemic. They raised concerns about excessive vaccination activities, risks of side-effects of certain vaccines, the ineffectiveness of some of the medication, as well as possible undue influence by biased advisors[13]. It was precisely these warnings which drew the Parliamentary Assembly’s attention to the issue and prompted it to take up the topic and ask for the preparation of the current report.

[7] WHO: Pandemic (H1N1) 2009 – Weekly update 90, 5 March 2010.
[8] 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 126th session, Geneva, Switzerland, 18 January 2010.
[9] WHO: Pandemic (H1N1) 2009 vaccine deployment update – 14 May 2010
[10] European Commission / Directorate of Health and Consumers: Pandemic (H1N1) 2009 – Factsheet, March 2010.
[11] WHO: Pandemic (H1N1) 2009 vaccine deployment update – 31 March 2010
[12] See for example The Parliamentary Office of Science and Technology (POST) of the United Kingdom, Postnote 331 in May 2009, London, saying: “The Department of Health (DH) has ‘sleeping contracts’ with two manufacturers (Baxter and GSK) which reserve a certain number of doses of any vaccine developed against a pandemic flu strain.”
[13] See interviews with epidemiologist Tom Jefferson of the Cochrane Collaboration: “A whole industry is waiting for a pandemic”. Der Spiegel (Germany), 21 July 2009, and with Prof. Marc Gentilini : Pour Marc Gentilini, on assiste à une "pandémie de l'indécence", Le Monde, 06.08.09.

III. Handling the H1N1 pandemic - transparency and accountability of public health action ?

13. All arguments presented by critics in recent debates seem to have one common focal point: the disparity between the relatively mild unfolding of the influenza as it appeared in the autumn of 2009, and the far-reaching action taken at European and national level in some countries. The criticisms raised by various international experts with regard to the way in which the H1N1 pandemic was handled are focused on some of the specific measures taken by the various stakeholders concerned notably WHO, the pharmaceutical groups, national governments and European Union bodies. The rapporteur's analysis therefore focuses on their respective action with a particular emphasis on decision-making processes in and around WHO. It was the declaration of a pandemic by WHO on 11 June 2009 and its subsequent recommendations which triggered the international agenda setting process and subsequent action for the implementation of vaccination strategies ; the role of WHO therefore merits special attention.

14. The rapporteur would like to point out that this analysis of the H1N1 pandemic was an extremely complex issue given that the actions taken by all stakeholders were closely intertwined. The research process of the Parliamentary Assembly itself seemed to have had an influence on some of the subsequent reactions of responsible organisations triggering review processes. In this respect the rapporteur welcomes the general readiness of organisations concerned to enter into an open dialogue with the Parliamentary Assembly. Not all questions have however been answered and some of the most sensitive issues still need to be dealt with.

a) The role of the World Health Organization (WHO)

15. According to its Constitution[14], the objective of the World Health Organization (WHO) shall be the attainment by all peoples of the highest possible level of health. It coordinates and directs international health work, provides technical assistance and aid in emergencies. It develops an informed public opinion on health matters and seeks to eradicate epidemic, endemic and other diseases. WHO is therefore the international authority on public health recommendations for the 193 member states of the Organization. In the light of its overwhelming success regarding the eradication of major human diseases (such as smallpox) and the control of others, WHO rightly benefits from its member states' highest respect and active support and collaboration through specially designed governance structures.

Governance system of WHO and bodies concerned by pandemic situations

16. The *World Health Assembly* is the supreme decision-making body of WHO. It generally meets in Geneva and is attended by delegations from all member states. Its main function is to determine the policies of the Organization. The Health Assembly appoints the *Director-General*, supervises the financial policies of the Organization, and reviews and approves the proposed programme budget. It similarly considers reports of the Executive Board, which it instructs in regard to matters upon which further action, study, investigation or report may be required. The WHO *Executive Board* is composed of 34 members technically qualified in the field of health and members are elected for three-year terms. Member states of WHO are further represented in six Regional Committees meeting yearly.

17. One of the main WHO bodies concerned in situations related to pandemic diseases is the *Strategic Advisory Group of Experts (SAGE),* serving as the principal advisory group for the development of policy related to vaccines and immunization at a strategic rather than a technical level. The SAGE comprises 15 members who are appointed for an initial term of three years (to be renewed only once), who serve in their personal capacity and who represent a broad range of disciplines proportionally represented in both geography and gender. SAGE's terms of reference as well as its list of members are made available through the WHO website. Before being appointed, all members have to sign a declaration of interest with the purpose of excluding conflicts of interest between any of their professional activities and their advisory function within WHO.

18. Under the provisions of the International Health Regulations (IHR) of 2005 , the WHO Director-General may also appoint an *Emergency Committee* for special advice on matters related to acute public health events and emergencies of international concern. In response to cases of swine influenza A(H1N1), reported in Mexico and the United States of America, the Director-General convened a first Emergency Committee meeting on 25 April 2009 to assess the situation and advise her on appropriate responses. The membership

[14] Articles 1 and 2 of the WHO Constitution as adopted by the International Health Conference held in New York on 22 July 1946 by the representatives of 61 States and entered into force on 7 April 1948 (and as amended in 1977, 1984, 1994, and 2005 respectively).

of this Committee is not public. It is on the basis of advice from this Committee that WHO declared the H1N1 pandemic on 11 June 2009.

Proportionality and appropriateness of the response

19. When looking at the still very moderate expression of the pandemic almost one year after its outbreak (May 2010), the interpretation of scientific and empirical evidence can be seriously questioned. For some experts, it seemed obvious from a relatively early stage that the new sub-type of influenza virus was doing less harm to persons infected than other forms of the virus in previous years. As one epidemiologist stated: "the importance of influenza is completely overestimated. It has to do with research funds, power, influence and scientific reputations"[15]. For those however in favour of far-reaching measures, these considered them justified by the 'precautionary principle'. It would appear that 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. Moreover, the possible mutation of the swine flu virus was considered as its greatest danger as this could have made both existing flu medication and vaccines ineffective, and could have increased the severity of the disease, as well.

20. According to some critical experts, it was precisely this lack of watertight evidence about the influenza phenomenon which led to the fears of the pandemic being exaggerated and the subsequent disproportionate response. Apparently, even for health experts and medical professionals it was difficult to clearly distinguish between influenza and influenza like illness which caused an overall impression that the pandemic was worse than it in fact was. In this respect, Dr Tom Jefferson of the Cochrane Collaboration[16], at a Parliamentary Assembly hearing held in Paris on 29 March 2010, stated that "few (if any) national and international surveillance systems make the distinction between influenza and influenza-like illness, either because they do not believe the question is important, because the 'system' is not geared up for it or for other still unclear reasons". He further noted that only 7-15% of people with flu symptoms truly have influenza. In other words, vaccination programmes are directed against what surveillance systems worldwide call "influenza", but in reality are influenza-like illness or flu. In advancing this data, he expressed the concern of certain critical experts as to whether the response to the H1N1 situation was appropriate. Furthermore, many countries have had difficulties in clearly distinguishing 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), which might have 'falsified' some of the statistics on which later public health decisions were founded. Very recently, Dr Klaus Stoehr, who was until 2007 in charge of WHO's pandemic preparedness, reinforced doubts about the appropriateness of the response given to H1N1 influenza by saying: "The pandemic planning I was involved with was always based on a severe public health event. [...] Moving to Phase 6 meant that we wanted governments [...] to kick in their plans whether they thought it was urgent or not". He then further expressed his belief that moving to Phase 6 that early was, in hindsight, not needed, and that WHO, over the course of summer 2009, had failed to read the signs about swine flu coming from the southern hemisphere[17].

21. The Parliamentary Assembly fully supports the responsible use of 'precautionary approaches' in public policies, as stated in its Recommendation 1787 (2007) on "The precautionary principle and responsible risk management". In a direct exchange with WHO representatives, the rapporteur nevertheless raised the question as to why WHO maintained the highest alert levels, even when empirical evidence had already shown that the pandemic turned out to be much milder than initially expected. In reply, Dr Keiji Fukuda, Special Advisor on Pandemic Influenza to the Director-General, stated 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 was 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 and considered the action followed in relation to the H1N1 virus as being justified[18]. In his statement made in

[15] See interview with epidemiologist Tom Jefferson of the Cochrane Collaboration: "A whole industry is waiting for a pandemic". Der Spiegel (Germany), 21 July 2009.

[16] The Cochrane Collaboration (Working together to provide the best evidence) for health care is a not-for-profit international network of researchers, practitioners and consumers who prepare and update systematic reviews of the effects of healthcare interventions (drugs, vaccines, devices, procedures, service delivery, training, quality control mechanisms etc). Cochrane reviews seek to bring together all of the research on a topic, to minimise bias and to provide independent, reliable information to help decision makers. There are now more than 4 000 full Cochrane reviews. The Collaboration has a structure including thirteen Cochrane Centres and just over 50 Cochrane Review Groups spread around the world – www.cochrane.org

[17] "WHO faces questions over swine flu policy", BBC News, Geneva, Thursday 20 May 2010.

[18] Quoting from the exchange of views with Dr Keiji Fukuda, Special Advisor on Pandemic Influenza to the Director-General of WHO, at the public hearing organised by the Social, Health and Family Affairs Committee in Strasbourg on 26 January 2010.

January 2010, he further added that it was too early to say whether the pandemic was over and that another significant wave could still be expected across Europe in the winter or spring.

22. It is clear to the rapporteur that the proportionality of the response to the H1N1 influenza needs to be evaluated, and that WHO and member states need to consider this in the context of the review processes that have been set up or are being set up in the light of the debate on the pandemic. Furthermore, all public health authorities concerned should critically review their way of dealing with the precautionary principle, including the communication about its use, given that the question of what society should do in the face of uncertainty is necessarily a question of public policy and not only a question of science. In future situations posing a serious risk to public health, decision-makers should bear in mind that the precautionary principle can contribute to a general feeling of anxiety and unease in the population and can fuel the media in what becomes a cycle of fear mongering.

23. In a situation where uncertainty is coupled with risks for human health and lives, there is also a danger that public opinion can be manipulated in favour of particular commercial interests. In addition, it should be recognised that there is a danger that policy makers are forced to make choices not dictated by the search for the optimal solution, but rather a solution that would protect them from accusations (the so-called umbrella phenomenon).[19] In the view of the rapporteur it is therefore of utmost importance that vital decisions regarding public health threats, notably when placed in a context of uncertainty, are taken in a fully transparent way. Furthermore, complete information needs to be provided to the public in a manner which allows even those with little scientific knowledge to follow the arguments in a dispassionate manner. In this respect, the rapporteur recognises that assessing and communicating the impact of a virus is difficult and that only in retrospect can one say what is a severe or mild to moderate level of pandemic. However, in order to avoid what has been called the “concern bias”, in which anxiety drives reactions to a greater extent than the disease itself, some commentators have recently called for a more calibrated approach to emerging infections and the need to reassess both the risk assessment and risk management strategies[20].

Changing the definition of a pandemic

24. A number of members of the scientific community became concerned when WHO rapidly moved towards pandemic level 6 at a time when the influenza presented relatively mild symptoms. This combined with the change in the definition of pandemic levels just before the declaration of the H1N1 pandemic heightened concerns. As Dr Wolfgang Wodarg, German epidemiologist and former member of the Parliamentary Assembly highlighted at the public hearing on 26 January 2010, the declaration of the current pandemic was only made possible by changing the definition of a pandemic and by lowering the threshold for its declaration.

25. WHO continues to assert that the basic definition of a pandemic was never changed. Only the description of pandemic alert levels was revised when the document “Pandemic Influenza Preparedness and Response: A WHO Guidance Document” (new title) was updated in May 2009. Notwithstanding these assertions, there is clear evidence that changes were made and that, most importantly, the former criteria of ‘impact and severity’ of an epidemic in terms of the number of infections and deaths was no longer considered relevant in the updated document[21]. In other words, the pandemic could be declared without the need to show that it was likely to be severe in terms of its impact on the population (for example regarding severity of illness and death). The definition before 4 May 2009 was worded as follows: “An influenza pandemic occurs when a new influenza virus appears against which the human population has no immunity, resulting in epidemics worldwide with enormous numbers of deaths and illness. With the increase in global transport, as well as urbanization and overcrowded conditions, epidemics due the new influenza virus are likely to quickly take hold around the world”, whilst the same definition became the following on WHO’s website after this date: “A disease epidemic occurs when there are more cases of that disease than normal. A pandemic is a worldwide epidemic of a disease. An influenza pandemic may occur when a new influenza virus appears against which the human population has no immunity …. Pandemics can be either mild or severe in the illness and death they cause, and the severity of a pandemic can change over the course of that pandemic”.

26. Shortly afterwards, WHO spokeswoman Nathalie Boudou justified the change by saying that the “old” definition was in “error” and had been removed from the WHO website. She stated that the correct definition was that a "pandemic indicated outbreaks in at least two of the regions into which WHO divides the world,

[19] Elisabeth Fisher: “Is the precautionary principle justiciable?” Journal of Environmental Law, Vol. 13, N 3, Oxford University Press.
[20] Peter Doshi: Calibrate response to emerging infections, BMJ 2009, 339:b3471
[21] WHO: Pandemic influenza preparedness and response: a WHO guidance document, May 2009.

but has nothing to do with the severity of the illnesses or the number of deaths".[22] These subsequent definitions and comments presented at a time when the pandemic was imminent were confusing for both public health professionals involved and attentive observers amongst the European public at large.

27. The rapporteur strongly recommends that further in-depth work be done by all stakeholders concerned with a view to agreeing on a common definition and description of what an influenza pandemic is. This should become the central element of clear international guidelines for national pandemic preparedness planning. He considers that, even if WHO did not intend to modify the pandemic definition in a way that would allow for an accelerated announcement of such an event in June 2009, the changes of relevant disease descriptions and indicators at a time when a major influenza infection was already approaching was highly inappropriate and carried out in a way which could be considered as being non-transparent. It also contributed to the doubts raised concerning undue influence on decision-makers, because all critical observers of the situation wondered if this untimely change was absolutely necessary and question who benefited most from it.

Public-private partnership under scrutiny

28. Public-private partnerships were introduced into the governance system of WHO following a call in 1993 by the World Health Assembly to mobilise and encourage the support of all partners in health development, including NGOs and institutions in the private sector. This substantial change in its working methods had the positive intention of "mobilising privately funded resources and expertise for the benefit of public health, whilst giving the commercial sector the opportunity to attract new investors and establish new markets through an improved corporate image". However, WHO successively developed institutional safeguards to counterbalance potential risks of public-private partnerships, and published its guidelines on working with the private sector to achieve health outcomes in 2000. When it introduced mechanisms intended to safeguard its integrity, WHO found itself directly at the centre of a debate on the appropriateness of public-private cooperation. At the time, the precautions taken were welcomed by some critics but many saw them as inadequate both in substance and process. [23]

29. The rapporteur believes that, despite greater awareness of the risks of public-private partnership today and the development of routine safeguards against conflicts of interests within WHO governance bodies, continued attention should be given to this issue. In a world characterised by a high level of access to information technologies where lobbying activities and relevant networks of interest groups are increasingly internationalised and professionalised, the problem of possible conflicts of interest of health experts is more topical than ever. It is precisely in this context that the Parliamentary Assembly adopted its Recommendation 1908 (2010) on "Lobbying in a democratic society" in which it stated that unregulated or secret lobbying may be a danger and can undermine democratic principles and good governance. With regard to the public health sector, the rapporteur is notably concerned by the systematic recruitment of so-called "key opinion leaders" by specific "image and communication agencies" in the pharmaceutical industry[24].

30. For the rapporteur, the possibility that representatives of the pharmaceutical industry may have directly influenced public decisions and recommendations made with regard to the H1N1 influenza remains one of the central issue of the ongoing debate. Amongst the factors leading to the suspicion of undue influence were the early measures taken on contractual arrangements for vaccine delivery between member states and pharmaceutical companies, as well as the enormous profits that companies were able to make as a result of the pandemic. The main suspicion, however, arises with regard to the issue of whether members of WHO advisory bodies have professional links to pharmaceutical groups, bringing into question the neutrality of their advice. Unfortunately, due to WHO's refusal to release the names and declarations of interest of persons concerned, any current research on the matter depends entirely on the results of investigative journalism[25].

31. Neither of the WHO advisory bodies, SAGE nor Emergency Committee, have any executive or regulatory functions. Their members are appointed by the Director-General of WHO according to the so-called IHR Expert Roster and in compliance with the WHO Advisory Panel Regulations. The Organization admits that, when reaching out to a broad group of experts and interest groups, there is always a potential risk of conflicts of interest in the advice given, but that possible conflicts of interest are countered by a

[22] All quotations compiled by Dr Tom Jefferson, Cochrane Collaboration, and presented at the public hearing of the Social, Health and Family Affairs Committee of the Parliamentary Assembly in Paris on 29 March 2010.
[23] Kent Buse & Amalia Waxman: Public-private health partnerships: a strategy for WHO, Bulletin of the World Health Organization, 2001, 79 (8)
[24] Dr Tom Jefferson in his statement made at the public hearing of 29 March 2010
[25] Stéphane Horel: "Les Médicamenteurs – Labos, Médecins, Pouvoirs publics : enquête sur des liaisons dangereuses", Editions du moment, Février 2010.

number of routine safeguards. According to WHO, transparency is ensured by declarations of interest in which 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. According to senior WHO officers, biased recommendations are prevented by only allowing those experts who have no perceived or real conflicts of interest to make recommendations. Finally, the relative weight of those who declare a conflict of interest is also an element to be taken into account in WHO's view: if a conflict of interest appears regarding a person who could otherwise give valuable input, the person concerned is only allowed to participate in the general exchange of views and communication. Although this approach reveals a certain degree of awareness of this sensitive issue, the rapporteur is not convinced that it represents a sufficient safeguard against possible conflicts of interests, and thus undue influence and bias.

33. The main focus of criticism is the Emergency Committee directly advising the Director-General on the H1N1 pandemic. This Committee has met a total of eight times since the outbreak of the pandemic (meetings held between April 2009 and May 2010). After reviewing available data on the current situation, Committee members identified a number of gaps in knowledge about the clinical features, epidemiology, and virology of reported cases and the appropriate responses. The Committee advised that answers to several specific questions were needed to facilitate its work, but generally agreed that the current situation constituted a public health emergency of international concern.

34. Although critical voices from various countries and the Parliamentary Assembly itself[26] have on several occasions called for the list of experts and their respective declarations of interest to be published, WHO has failed to provide this information. The Organization continues to hold back on releasing further information on the interests of experts, justifying this position by the need to protect experts' privacy and to prevent them from coming under extreme pressure from certain private companies or interest groups. The rapporteur is very concerned by this attitude and remains convinced that it is entirely justified to require full transparency with regard to the profiles of experts whose recommendations have far-reaching consequences for the public health sector and the health and well-being of Europeans.

35. The rapporteur would like to highlight that some degree of understanding of the doubts concerning the neutrality of advice could be found even within WHO itself. The Organization recently acknowledged 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"[27]. At the same time, WHO stated more than once that it considered existing mechanisms to be satisfactory, but declared its intention to respond to allegations of undeclared conflicts of interest, which it claimed to take very seriously. As early as January 2010, WHO announced its intention to launch a review of the way in which the ongoing pandemic was handled, including an evaluation of its own performance, with the participation of external experts and with a view to reviewing existing International Health Regulations (IHR).

36. As announced in January 2010[28], an internal review process was launched by WHO through the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009. It met for the first time on 12-14 April 2010 in Geneva. According to its first report, the Committee pursued a threefold objective (1) to assess the IHR in relation to the current pandemic, (2) to review the scope, appropriateness, effectiveness and responsiveness of global action as well as the role of the WHO Secretariat, and (3) to identify and review the major lessons learnt from the global response to the current pandemic.

37. The rapporteur commends this critical and self-critical approach taken by WHO regarding the H1N1 pandemic and the current loss of confidence amongst Europeans, both members of the public and decision-makers. The rapporteur requests that the critical issues raised in the present report should be taken up comprehensively during the review process which is under way. He strongly advises WHO and other institutions concerned to explicitly open up their policy guidance process to experts with diverse or contrary views in order to avoid what could be referred to as "group think". In this respect, the rapporteur very much welcomes the fact that the WHO Review Committee, which has just taken up its work, is chaired by Professor Harvey V. Fineberg, President of the Institute of Medicine of Washington D.C. (USA), who stated in 1978: "In a swine flu case when evidence is thin […] it is not only the assumptions but appraisal of their

[26] Request addressed by several parliamentarians to WHO representative Dr Keiji Fukuda at the public hearing organised by the Parliamentary Assembly's Social, Health and Family Affairs Committee on 26 January 2010.
[27] WHO: Pandemic (H1N1) 2009 briefing note 19, 3 December 2009, Geneva.
[28] 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.

scientific quality that top decision-makers need. Panels tend toward 'group think' and over-selling, tendencies nurtured by long-standing interchanges and intimacy, as in the influenza fraternity. Other competent scientists, who do not share their group identity or vested interests, should be able to appraise the scientific logic applied to available evidence"[29].

Communication and dialogue on sensitive health issues

38. In addition to the substantial advice given by WHO and other major stakeholders, and to the way in which it was prepared, a critical view is also justified regarding the – sometimes ambiguous - way in which issues related to the H1N1 pandemic were communicated to national governments and the European public at large. In this respect, the rapporteur wishes to highlight the regular overstatement of the pandemic's expected outcome in terms of infections and deaths which nourished increasing uncertainty and fears amongst Europeans. A review is also necessary of the media's role in fuelling fear and how WHO and how national authorities should handle communications in the future, in particular when applying the precautionary principle.

39. WHO itself continues to assert that it has consistently evaluated the impact of the current influenza pandemic as moderate, reminding the medical community, public and media that the overwhelming majority of patients experience mild influenza-like illness and recover fully within a week, even without any form of medical treatment[30]. Most people, however, expected more dramatic consequences, not least because in spring 2009, the approaching swine flu was repeatedly compared to previous infectious diseases, notably the avian flu and SARS in more recent years, but also the Spanish flu of 1918. For some experts, such as Professor Keil, epidemiologist and Director of WHO Collaborating Centre on epidemiology of the University of Münster (Germany) who was heard at the public hearing of 26 January 2010, 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. In reacting to this, WHO stated that reference to former health events should be taken as a positive sign: the Organization for example pointed to the success in limiting the spread of SARS as a major public health victory[31].

40. In recent debates, WHO furthermore declared itself aware that preparing and communicating information on complex public health matters had become a major challenge in the globalised context of the 21st century, in view of the fact that information is more decentralised and expectations of the population are much higher. There are now not only traditional news services but also blog sites, email and a number of other sources of information which have to be taken into account. The rapporteur considers that much more will need to be done in the future to improve dialogue and communication on sensitive public health matters at international, European and national levels.

b) The role of the pharmaceutical industry

41. A number of vaccine manufacturers are involved with the production of H1N1 vaccines at international level[32]. At European level the vaccines - Focetria of Novartis, Pandemrix of GlaxoSmithKline, Celvapan of Baxter International as well as Panenza of Sanofi-Pasteur - were used during the H1N1 pandemic. These companies are organised in the European Vaccine Manufacturers Group EVM belonging to the European Federation of Pharmaceutical Industries and Associations (EFPIA).

42. Through EVM, the pharmaceutical industry was represented in the public hearing on 26 January 2010. According to EVM, 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.[33]

[29] Neustadt and Fineberg in their review of the 1976 "swine flu fiasco": The Swine Flu Affair, 1978:89.
[30] See statement by WHO Director-General, Dr Margarat Chan, on 29 April 2010
[31] Dr Keiji Fukuda, Special Advisor to WHO Director-General on Pandemic Influenza, at the public hearing organised by the Parliamentary Assembly's Social, Health and Family Affairs Committee on 26 January 2010.
[32] Names regularly referred to by the specialised press include: Novartis, GlaxoSmithKline, Sanofi-Aventis, Astrazeneca, Sinovac, Baxter International, Inovio Biomedical, Novavax, CSL, Solvay, Hualan Biological, Green Cross.
[33] European Vaccine Manufacturers (EVM) statement on Council of Europe debate on 'Faked Pandemics – a threat for health', edited on 14 January 2010, Brussels. Statement presented by Dr Luc Hessel, EVM, at the public hearing on 26 January 2010.

43. The role of the pharmaceutical industry is closely linked to the issue of prevailing procedures for drug evaluation and authorisation and the degree of transparency characterising them. According to the information given to the rapporteur, all vaccines used during the pandemic were authorised according to the formal procedure followed by the European Medicines Agency (EMEA) although not all of them were clinically tested on vulnerable persons such as children[34]. In its official statements, the Agency asserted that, despite the short delays within which vaccines were authorised, they had been sufficiently tested, along with the adjuvants used[35]. Whether or not there was sufficient testing remains highly controversial within the medical community. There is, however, evidence that at least one vaccine without adjuvants made by Sanofi-Pasteur (Panenza), was treated differently and was able to receive national authorisation in some countries, such as France, without passing through some of the rigid European procedures[36]. Without wishing to take a definitive stance on this highly specific question here, the rapporteur considers it entirely justified to ask whether scientific evidence was sufficient to remove any remaining doubts about the relevant products.

44. The most crucial question in this respect concerns the possible risks taken with regard to the health of those persons taking the vaccines and anti-flu medication, and notably the most vulnerable groups (such as children, pregnant women or chronically ill persons). Some critical experts had already pointed out that side-effects or effectiveness of vaccines and antiviral medication (such as Tamiflu or Relenza) had not been sufficiently tested before their commercialisation. This notably concerned some of the vaccines which were developed by using specific patented adjuvants or breeding layers for the virus antigen to come. The fact that only patented products received authorisation was the reason why the vaccines could be monopolised by a few companies and sold at much higher prices than seasonal vaccines, which are traditionally produced in chicken eggs and could have been provided much faster by many laboratories all over the world using non-patented procedures.[37] A few months after the declaration of the pandemic, even the European Medicines Agency pointed out that "only limited data on the safety and immunogenicity of influenza A(H1N1)v vaccines will be available when member states start to use the vaccines. In addition, due to the possible mutation of the virus, the effectiveness of the vaccines will need to be followed."[38]

45. Critical experts also wondered about the general need of developing a special vaccine aimed at H1N1 influenza. Given that new flu virus variations are detected almost every year, the virus could possibly have been treated by flu vaccines in stock, instead of having to produce a special product in a very short time, thus speeding up some of the authorisation procedures as described above. Finally, and closely linked to the above health aspects, the rapporteur considers it important to raise the question of whether national governments were well advised by health authorities before purchasing great quantities of vaccines authorised in fast-track procedures. This particularly concerns the initial advice that double doses were necessary. For the rapporteur it is clear that the way of dealing with vaccines through accelerated evaluation and authorisation procedures reinforced the exposure of national governments to the possible pressure of pharmaceutical groups and the suspicion of undue influence on public health decisions.

46. Another factor which nurtured suspicions about undue influence was that the pharmaceutical companies had a strong vested interest in the declaration of a pandemic and subsequent vaccination campaigns. This interest arose partly from early 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[39]. Whilst this anticipation of a major public health event by governments and pharmaceutical groups could be generally welcomed, the rapporteur would like to point out that there is evidence of doubtful commercial practices followed by some industrial groups. The rapporteur refers in particular to pressure exerted on national governments to activate "sleeping contracts" after very short delays of reflection (using the argument of "first come – first served") and the attempt to transfer the main responsibility for side-effects of vaccines to the governments themselves (see the experience of Poland described later). Following these suspicions, and in light of the major impacts on public health budgets all over Europe, the rapporteur

[34] EMEA: 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.
[35] 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, such as Squalene or Thiomersal (Sources: EMEA and Prof. Daniel Floret, Technical Director of the High Council of Public Health in France, September 2009)
[36] Stéphane Horel : "Les Médicamenteurs – Labos, Médecins, Pouvoirs publics : enquête sur des liaisons dangereuses, Editions du moment", Février 2010.
[37] As described by Dr Wolfgang Wodarg, epidemiologist at the public hearing of 26 January 2010.
[38] European Medicines Agency (EMEA): Explanatory note on scientific considerations regarding the licensing of pandemic influenza A(*H1N1)v vaccines, London 24 September 2009.*
[39] Idem as footnote 12

welcomes the willingness of pharmaceutical groups to step back from contractual arrangements made with national governments and allow them to opt out of some of the orders not yet delivered.

47. The strong commercial interests in the pandemic and vaccination campaigns were further illustrated by the high levels of profit that pharmaceutical companies were able to make. 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[40]. As such, and from the point of view of the market economy, justified commercial interests cannot be generally criticised. The rapporteur would, however, like to raise the question as to whether it was justified to sell H1N1 vaccines to national governments at prices seemingly up to 2 to 3 times higher than those for the usual seasonal influenza by primarily using patented adjuvants, and thus making exaggeratedly high profits from a declared public health emergency?

48. Concluding on the current role of the pharmaceutical industry, the rapporteur considers that – whilst public authorities need to further strengthen safeguards with regard to excluding any conflicts of interest, and while there was a general willingness of pharmaceutical groups to participate in a dialogue – additional efforts are needed from industrial players to prove that they are not exerting undue influence on public health decisions and drawing unreasonably high returns from emergency situations. In the same way that confidence needs to be rebuilt in public health action, it is necessary to consolidate trust in science and medicine by all possible means, including the involvement of a broad range of scientific expertise. The case of the H1N1 pandemic also raises challenging questions about the system by which drugs are evaluated, regulated and promoted. When vast quantities of public money and large amounts of public trust are placed in drugs, the full data must be accessible for scrutiny by the scientific community[41].

c) The role of member states and their health authorities

49. Member states have to address a complex set of issues related to the H1N1 pandemic which can be summarised in two central questions: Firstly, were they well advised regarding pandemic preparedness strategies, and secondly, did they act in a responsible manner with a view to their citizens' health and well-being? For this report a number of national reactions were examined. The rapporteur does not intend to judge, on behalf of all Council of Europe member states, if the matter was dealt with appropriately or not. It will be up to each member state to address the questions highlighted in the current report and draw its own conclusions.

50. Just as different members of the medical community are divided in their positions, Council of Europe member states showed different reactions to the H1N1 pandemic, ranging from very reserved attitudes and low-profile vaccination campaigns (Poland), to highly pro-active approaches to pandemic preparedness (United Kingdom and France). However, lingering concerns and the lack of scientific evidence about the effectiveness and possible side-effects of vaccines led to a clear decrease in the demand for the new vaccine amongst the population of many countries. Thus, in December 2009, many countries such as Germany, France, the United Kingdom, Italy and Ireland reported that only about 10% of the population had been vaccinated. It was this low level of demand which finally led to the perception of public budgets having been wasted on the H1N1 pandemic, given that great quantities of vaccines ordered by many governments were never used.

51. In order to better understand some of the decisions taken at national level and their motivations, the rapporteur took a closer look at the way in which the pandemic was handled in the United Kingdom, France and Poland. These countries showed some of the most extreme reactions to the announcement of the pandemic in June 2009. The British Department of Health initially announced that approximately 65 000 deaths were to be expected. At the beginning 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 360 deaths had been noted. In March 2010, the rapporteur had the occasion to meet with Gillian Merron, then 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.

52. The figures available for France illustrate very well the extent to which the H1N1 pandemic was overstated and the consequences for the public health budget: 312 people died of influenza (up to April

[40] Agence France Presse (AFP) on 9 February 2010.
[41] Fiona Godlee, Mike Clarke: "Why don't we have all the evidence on oseltamivir?", BMJ 2009, 339: b5351.

2010), whilst 1 334 cases of serious infection were registered since the beginning of the pandemic according to the National Institute for the monitoring of health issues ("Institut national de veille sanitaire"). In the light of the actual development of the H1N1 pandemic, the French government managed to cancel orders for 50 million doses of vaccine, out of a total of 94 million initially ordered. Vaccines were sold on to some other countries, however France was left with millions of unnecessary doses as only 5.7 million people were vaccinated by March 2010. The final French public health bill for vaccines amounted to 365 million Euros and a stock of 25 million doses of vaccine whose shelf life will expire at the end of 2010[42]. The rapporteur considers that with hindsight it can be concluded that France is not in an enviable position. France, however, is not alone in this situation.

53. In the light of this evidence, some of the critical issues raised in this report, have now been addressed at the national level in France. Critical observers of the pandemic in France have openly questioned the neutrality of "independent experts" present in some of the official national bodies, such as the Committee for fighting the influenza ("Comité de lutte contre la grippe")[43]. The National Assembly and Senate have taken a proactive approach by organising 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[44]. The French Senate 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. The National Assembly has launched a parallel procedure through its "Investigation committee on the way in which the vaccination campaign against Influenza A (H1N1) was planned, explained and handled". The committee is due to present its report on 13 July 2010.

54. Certain member states did not rush into taking action following the announcement of the pandemic. Poland, for example, is one of the few countries in Europe not to have purchased large quantities of vaccines due to safety fears and distrust of the pharmaceutical companies producing them. At the public hearing organised by the Assembly in Paris on 29 March 2010, the Polish Health Minister, Ms Ewa Kopacz, described the Polish approach to preparing the pandemic. She explained that it was undertaken in close collaboration with the European Centre for Disease Control and Prevention (ECDC) and national centres. It included a thorough analysis taking care to combat panic and general social unease by the public at large. The Polish Flu Pandemic Committee defined a high risk group of 2 million persons and set aside resources to buy appropriate numbers of vaccines. However, the Minister considered that the conditions proposed by the pharmaceutical companies for the purchase of vaccines were unacceptable. Vaccines were to be purchased only by the government (not marketed to private individuals), and the government was asked to take full responsibility for all undesirable side effects (the threat of which seemed real according to the Eudravigilence system). Furthermore, the vaccines were offered at up to 2 to 3 times the price of vaccines used against seasonal influenza. As the Polish Minister herself emphasised during the public hearing in March 2010, she took the responsibility – as a politician and medical doctor - not to accept these conditions and avoid becoming hostage to private interest groups or being obliged to take major decisions resulting from alarmist announcements.

55. Following some of the widely debated criticisms of the handling of the H1N1 crisis, many member states have de-intensified their vaccination campaigns and managed to divest themselves of 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 under strain during the economic crisis. The rapporteur recognises that the damage to public health budgets has been slightly limited in this way. He is nevertheless concerned by the distortion of public health priorities during the course of the last year, and the enormous sums of money which could have been used for many other, often more urgent, health issues. He is convinced that the Parliamentary Assembly should strongly encourage Council of Europe member states in the future to take a more critical stand when it comes to future pandemic warnings. Moreover, they should themselves review the way in which the H1N1 pandemic was handled at national level by following the examples of countries that have already started to review their handling of the pandemic (such as France).

56. The Parliamentary Assembly should encourage member states to closely follow relevant review processes recently launched within WHO and European institutions involved in public health matters, in order to ensure that their voices may have more impact in future pandemic situations than seems to have

[42] Various press articles, such as Reuters on 25 February 2010 and Ouest France on 25 March 2010.
[43] Stéphane Horel : Les Médicamenteurs – Labos, Médecins, Pouvoirs publics : enquête sur des liaisons dangereuses, Editions du moment, Février 2010.
[44] 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 ? »

been the case in the current H1N1 pandemic. There is strong evidence that some governments, including China, Britain, Japan and a dozen other countries, at some stage of the H1N1 pandemic, urged WHO not to use the proposed new definition of a "pandemic" and "be very cautious about declaring the arrival of a swine flu pandemic, fearing that a premature announcement could cause worldwide panic and confusion." In reply to their doubts, WHO said "it would certainly look at [this issue] very closely" just before declaring the pandemic on 11 June 2009.[45]

d) The role of European Union bodies

57. The specific role of European Union bodies involved in health issues has not been researched in detail for the purpose of the current report as the rapporteur wished to focus on the 'triangle of action' represented by WHO, national governments and the pharmaceutical industry. Their role in the H1N1 pandemic may therefore be mentioned as an element of background information allowing for a comprehensive understanding of the current situation and review processes just starting.

58. The central European body in charge of the Europe-wide authorisation of new medical products, including vaccines, is the European Medicines Agency (EMEA). Monitoring the progress of the H1N1 pandemic at European level has been and continues to be ensured through the European Centre for Disease Control and Prevention (ECDC). It has provided daily updates on the situation up to the beginning of 2010. Notwithstanding that ECDC considered that the pandemic was far from over and that considerable uncertainties remained, their Public Health Event Strategy Team (PST) decided to downgrade their crisis management activities in January 2010, thus ending the publication of the daily updates. After this date, the ECDC has nevertheless continued its work relating to the H1N1 pandemic under a reinforced general influenza programme[46]. The mission of the ECDC, established in 2005 and seated in Stockholm/Sweden, is to identify, assess and communicate current and emerging threats to human health posed by infectious diseases in partnership with national health protection bodies across Europe and by associating health experts throughout Europe. As with WHO, the ECDC relies on internal advisory bodies. The names and declarations of interest of experts on these bodies have still not been released either.

59. The European Commission is currently evaluating the management of the H1N1 influenza by their own institutions as well as by EU member states in the run-up 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).

60. Finally, an initiative to launch a comprehensive investigation process on the handling of the H1N1 pandemic by European institutions was undertaken within the European Parliament by Michele Rivasi, member of the Group of Greens/European Free Alliance. The Parliament decided on 20 May 2010 not to set up an investigation committee, leaving further follow-up open at this stage. The rapporteur has collaborated closely with Ms Rivasi who participated in the second hearing of the Social, Health and Family Affairs Committee on 29 March 2010. The rapporteur hopes that this fruitful collaboration between the European Parliament and the Parliamentary Assembly can be pursued in the future on other public health issues of European concern.

61. Although certain critical issues will have to be reviewed at European level (such as possible conflicts of interest of health experts and the transparency and outcomes of certain fast-track authorisation procedures for vaccines), the rapporteur generally welcomes the realistic approach taken on the pandemic by European institutions involved in public health matters who downgraded their alert systems at the beginning of 2010, as well as the critical review processes recently launched. He hopes that the European Commission will furthermore follow and contribute to the activities and debates on good governance in the public health sector at the level of the Council of Europe level, including at the level of the Parliamentary Assembly.

[45] As reported by Associated Press on May 19, 2009, and quoted by Dr Wolfgang Wodarg, German epidemiologist at the public hearing of 26 January 2010.

[46] European Centre for Disease Control and Prevention (ECDC): ECDC Daily Update on the 2009 influenza A(H1N1) pandemic, 19 January 2010.

V. Conclusions - Recommendations

62. In concluding the present report, the rapporteur remains greatly concerned with the way in which the 2009/2010 H1N1 influenza pandemic was handled and in particular with the transparency of some of the decisions taken. He considers that the debates and discussions held in the past months, including those in the framework of the Parliamentary Assembly, have already helped public health authorities analyse some of the issues being faced and given them encouragement to carry out their own review processes.

63. For the rapporteur, the main concerns regarding the current H1N1 influenza include the proportionality of the response given to the public health threat of H1N1, the transparency of relevant decision-making processes, including the possibility of undue influence by the pharmaceutical industry, and the way in which the pandemic, and the use of the precautionary principle, was communicated to member states' governments and to the European public at large, also by the media.

64. The rapporteur considers that some of the outcomes of the pandemic, as illustrated in this report, have been dramatic: distortion of priorities of public health services all over Europe, waste of huge sums of public money, provocation of unjustified fear amongst Europeans, creation of health risks through vaccines and medications which might not have been sufficiently tested before being authorised in fast-track procedures, are all examples of these outcomes. From the rapporteur's perspective, these results need to be critically examined by public health authorities at all levels with a view to rebuilding public confidence in their decisions. Public health authorities need to be better prepared for the next infectious disease of pandemic scope, which might be of greater severity.

65. Serious doubts unfortunately remain concerning the transparency of decision-making processes relating to the H1N1 pandemic. After having analysed relevant processes, the rapporteur is alarmed by the inappropriate timing and method of changing essential definitions related to pandemics as well as the possible influence of pharmaceutical groups on some of the central decisions taken. The rapporteur continues to be very concerned by the lack of transparency regarding the identity of experts whose recommendations have had a major impact on public health budgets and people's health. He considers that the right of 800 million Europeans in Council of Europe member states to be fully informed should prevail over the right of a relatively small number of experts to privacy.

66. Suspicion of undue influence and pressure put on national authorities by the pharmaceutical industry has been reinforced by other factors, such as the character of contractual arrangements concluded between governments and pharmaceutical groups. Reports from several European countries indicate that there was pressure exerted on national governments to speed up the conclusion of major contracts, that dubious practices were followed concerning prices of vaccines, which were not available under normal market conditions, and that there were attempts to transfer liability for vaccines and medication, which might not have been tested sufficiently, to national governments. The rapporteur considers that these incidences were most alarming. He encourages greater cooperation between national governments in order for them to be able to take coherent and strong stands when negotiating with large pharmaceutical groups in the future.

67. Finally, the rapporteur is very concerned about the way in which the information on the pandemic was communicated by WHO and national authorities to the public, the role of the media in this, and the fears that this generated amongst the public. The rapporteur recommends that a thorough review should be undertaken to ensure that coherent and sensitive communication strategies are prepared and followed in the future by all public health authorities whenever the next major situation arises which poses a serious threat to public health.

68. With regard to previous public health scares (avian flu, SARS etc.), the rapporteur is convinced that there is a real danger of now having cried 'wolf' so often that the public will not take appropriate notice anymore when the next infectious disease occurs. Many people might then decide not to get vaccinated and put their own health and lives, and indirectly those of others, at risk. Therefore, certain immediate efforts are required with a view to rebuilding public confidence in decisions and recommendations made by WHO and other public authorities concerned.

69. Conclusions from the handling of the H1N1 pandemic should, however, be drawn at different levels. With regard to immediate action to be taken, the Parliamentary Assembly should request that WHO and European institutions concerned, share some essential information, notably by publishing the names and declarations of interest of experts present on relevant advisory bodies who have had a direct influence on public health recommendations taken.

70. In order to provide substantial input to ongoing review processes, the Parliamentary Assembly should address all major stakeholders concerned, including WHO, European Union bodies dealing with health matters, and also national governments or parliaments. The Assembly should invite them to review their governance structures in the public health sector, agree on common definitions related to public health (such as pandemics), to revise existing guidelines for working with the private sector or prepare such guidelines where they do not exist and, finally, to entirely revise their communication strategies relating to sensitive public health issues. The Assembly should further ask for maximum transparency in all work undertaken.

71. Member states should be explicitly invited to follow-up on the conclusions of internal review processes undertaken within international and European institutions in order to make sure that they take into account all relevant recommendations including those of the Parliamentary Assembly. They should furthermore be invited to start relevant review processes at national level where they have not done so, and national parliaments should be involved in these processes.

72. The Parliamentary Assembly should also call upon the pharmaceutical industry to be aware of their corporate social responsibility with regard to major public health matters, and to act in the most transparent manner possible. Beyond their openness to participate in the public debates during recent months and directly respond to questions and criticism raised, international industrial groups should be ready to critically revise their own rules and functioning regarding cooperation with the public sector and their role in public health emergencies. Just as the World Health Assembly did in 1993 by calling for the introduction of public-private partnerships into WHO mechanisms, the rapporteur fully recognises the fact that the highly specialised knowledge in industrial companies makes them an indispensable partner for public health authorities. This should, however, not empower them to put public health authorities under pressure and commercialise their products with a view to making excessive profits in emergency conditions.

73. There are many organisations and institutions at international, European and national level which have been concerned by pandemic preparedness planning and the implementation of subsequent vaccination strategies during the H1N1 pandemic. At the level of the Council of Europe, good governance in the public health sector is addressed at a general level through intergovernmental cooperation activities related to the development of an ethical European health policy. In this respect, the rapporteur welcomes the recent adoption of Recommendation CM/Rec(2010)6 of the Committee of Ministers to member states on good governance in health systems which could become a valuable contribution to the creation of truly transparent public health systems in Europe.

74. The specific contribution of the Parliamentary Assembly in the current situation has been and will be to provide a European platform where issues relating to democratic accountability and transparency of public decision-making processes in the health sector have been and will continue to be debated. In addition to its contribution regarding the topical issue of the H1N1 Pandemic, the Parliamentary Assembly should organise more regular debates on good governance in the health sector with major international and European stakeholders, notably WHO and European institutions responsible for health matters.

The appendix to this report, containing the written replies provided by WHO on 17 May 2010 to the questions submitted by the rapporteur, can be found in a separate document.