

EN

EN

EN



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15.9.2009
COM(2009) 481 final

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

Pandemic (H1N1)2009

{SEC(2009) 1188}
{SEC(2009) 1189}
{SEC(2009) 1190}
{SEC(2009) 1191}
{SEC(2009) 1192}

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

Pandemic (H1N1)2009

1. INTRODUCTION

In April 2009, a novel strain of human influenza H1N1 was identified that had caused illness in Mexico and the United States first, in March and April 2009.

On 11 June 2009, the World Health Organisation (WHO) declared a pandemic caused by the novel influenza A(H1N1) virus, called 'pandemic (H1N1) 2009'. This declaration was in line with the WHO's global influenza preparedness plan where phase 6, the pandemic phase, is defined as the virus causing sustained community-level outbreaks in at least two countries in one WHO region and in at least one other country in a different WHO region. The declaration therefore reflected the spread of the new virus, not the severity of illness caused by it.

In 2005, in the aftermath of the A (H5N1) 'bird flu' outbreaks, the Commission adopted a Communication on Pandemic Influenza Preparedness and Response Planning in the European Community, which set out the objectives for each inter-pandemic and pandemic influenza phase and the action to be taken to achieve them at both national and Community levels¹. This plan has provided a basis for the preparedness and response to the current public health situation.

Today the European Union is better prepared than ever before to tackle cross-border and global health threats in general and Pandemic (H1N1) 2009 in particular. Member States and the Commission have legal and operational provisions in place to authorise pandemic vaccines and anti-viral medication after careful consideration of risks and benefits on the basis of available data in the current pandemic, allowing an adequate response to this pandemic (H1N1) 2009 situation.

Now there is a need for closer coordination across sectors and Member States, whether at Community, national, regional or local levels, to help to mitigate the societal impact of an influenza pandemic by means of appropriate preparedness and response planning within their individual remits.

The main objective of this Communication is the protection of public health, by ensuring the best possible protection of citizens against the current pandemic. To this aim, the Communication presents in a single document the key issues on the public health coordination on pandemic (H1N1) 2009 at the EU level and internationally. In addition, it aims to highlight the important cross-sectoral dimension of this pandemic. To this end, and in response to requests by the Council of Health Ministers, the Commission is also making available in parallel to the present text, five separate Commission staff working documents on vaccine development, vaccination strategies, joint procurement, communication to the public and support for third countries.

¹ COM(2005) 607 of 28 November 2005.

2. COMPLEMENTARY ACTION TO EU MEMBER STATES

Community action in the field of public health, as set out in Article 152 of the Treaty, must complement national policies and be directed towards improving public health, preventing human illness and diseases and obviating sources of danger to human health. The aim is to tackle the major health scourges by promoting research into their causes, their transmission and their prevention and to provide health information and education.

Community action in the field of public health must fully respect the responsibilities of the Member States for organising and delivering health services and medical care. In relation to the international collaboration necessary during a global outbreak such as this pandemic, Article 152 states that the Community and the Member States will foster cooperation with third countries and the competent international organisations in the sphere of public health².

A global pandemic is a cross-border health threat which affects not only public health but also society and economies within the EU. However, the technical capacity, budgetary resources and preparedness structures are not equivalent and equally available in every Member State.

Consequently, a coordinated and supportive EU-level approach to public health measures between the EU Member States can provide substantial benefits. Firstly, Member States can draw on the scientific advice and guidance of the European Centre for Disease Prevention and Control, thereby ensuring that national resources for scientific assessments are allocated more efficiently.

Secondly, coherent and agreed approaches between Member States authorities on issues such as travel advice or school closures contribute to a better public understanding and trust in public health measures. Thirdly, Europeans demand information on pandemic situation and how to protect themselves. Good, objective, up-to-date communication with the public and the media means no mixed or wrong messages between countries.

As a prophylaxis, vaccination is one of the most effective public health mitigation responses in a pandemic while for the treatment anti-viral medication remains a key option. Due to the limited global manufacturing capacity within a short time vaccines will only be available in the EU gradually. In addition, solidarity towards the third countries including developing countries is also an issue that can be best coordinated at the European level between the donors to ensure maximum benefits for the receiving countries addressed.

Availability of vaccines and stockpiling and access to anti-viral drugs is determined at national level and Member States have taken preparatory action in this respect. To support those Member States with fewer financial resources or adequate capacities, the Commission has been working with the EU Health Security Committee to explore ways to support Member States for procurement of vaccines.

3. BACKGROUND

On 30 April 2009, the Ministers of Health adopted Council conclusions on influenza A/H1N1 infection³. They highlighted the need to coordinate national measures in Europe and called upon the Commission to continue to facilitate information sharing and cooperation between the Member States, in particular on risk evaluation, risk management and medical countermeasures.

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12002E152:EN:HTML>

³ http://ec.europa.eu/health-eu/doc/council_concl.pdf

These coordination functions should be carried out in the Health Security Committee (HSC), the Early Warning and Response System for Communicable Diseases (EWRS) and the Committee of the Network for the Epidemiological Surveillance and Control of Communicable Diseases as well as with third countries and international organisations, in particular the WHO. The Commission has chaired joint meetings of Member States' EWRS national authorities and the HSC regularly since the beginning of the outbreak.

On 8 and 9 June the Council discussed vaccines and vaccination strategies against Pandemic (H1N1) 2009 and gave the HSC a mandate to work on these two issues. The Health Ministers met again informally on 6 and 7 July 2009 to discuss preparedness and response to Pandemic (H1N1) 2009, focusing on a Commission information note on vaccination policy and the outcome of the meeting of technical experts organised by the Swedish Presidency on 4 and 5 July 2009.

At international level, the Commission is a member of the Global Health Security Initiative on pandemic influenza and other health security-related issues bringing together G7 countries and Mexico. This network has been useful for sharing information between members on public health measures planned or taken.

The Global Health Security Initiative held informal meetings twice, first during the World Health Assembly in May and then, at the invitation of Mexico, in Cancun at a ministerial meeting on 2 and 3 July 2009 on Pandemic (H1N1) 2009. Another meeting was held in September in Brussels upon the invitation of the Commission.

4. EU COORDINATION ON PUBLIC HEALTH RESPONSE – JOINING FORCES WITH MEMBER STATES

The Commission monitors the situation internally and externally through various networks, expert groups and fora by which it enables exchange of information with MS and international organisations. The internal crisis management mechanism of the Commission (ARGUS) has been activated, enabling all affected services to jointly assess the multi-sectoral dimensions of this pandemic and respond accordingly.

In the health sector, the Commission cooperates closely with the scientific assessment agencies – the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA) – on specific issues and liaises closely with the WHO to ensure that measures taken at European Union level are in line with the WHO recommendations and international health regulations.

In order to ensure an effective, horizontal public health response to the pandemic at European level, as outlined in the Commission Communication on Pandemic Influenza Preparedness and Response Planning, the European Union has already taken a number of key measures using existing legal and public health mechanisms⁴:

- The common case definition, adopted in a Commission decision on 1 May 2009⁵;
- Agreement on advice to persons planning to travel to or returning from affected areas on 18 May 2009;
- Extension of the surveillance system to identify new cases in the EU on 18 May 2009;

⁴ These documents can be found on the Commission's dedicated website on Pandemic (H1N1) 2009: http://ec.europa.eu/health/ph_threats/com/Influenza/novelflu_en.htm.

⁵ OJ L 110, 1.5.2009, p. 58.

- Guidelines on case management and treatments and advice on medical countermeasures for health professionals on 18 May 2009;
- Advice for the general public on personal protective measures agreed and made available to Member States in all the official EU languages on 4 May 2009;
- Statements by the Health Security Committee and the Early Warning and Response System (EWRS) contact points on school closures and travel advice on 13 August 2009;
- Statement on ‘Vaccination strategies: target and priority groups’ agreed by the Health Security Committee and the EWRS contact points on 25 August 2009.

Decision 2119/98/EC⁶ places an obligation on Member States to report influenza outbreaks to the Community network on communicable diseases. They must give prompt notification of cases and then the Commission will transmit the information immediately to all the other Member States, prior to, where possible consultation and coordination of countermeasures by the Member States. The ECDC collects this information. In the case of pandemic influenza, daily situation reports are prepared for the Member States. ECDC is also providing ongoing support to Member States and the Commission in terms of surveillance and response to the crisis. This includes advice to the public on personal protective measures, and to Member States on mitigation activities⁷. The Community Civil Protection Mechanism is available to facilitate mutual assistance between Member States if national response capacities become overwhelmed. This may include immediate civil protection and medical assistance. Third countries can also appeal for assistance through this mechanism

As regards the authorisation of the necessary medicinal products, Community legislation sets out instruments which are well prepared for a pandemic through:

- Specific regulatory provisions for a fast-track scientific assessment and subsequent authorisation for marketing of human influenza vaccines and key medicinal products, such as anti-viral medication, in a pandemic situation.
- Specific regulatory provisions which allow Member States to take national decisions to authorise the distribution of unauthorised vaccines in an Influenza pandemic.

European Medicines Agency (EMA) provides scientific opinions on the risk-benefit evaluation of those medicinal products, including vaccines and anti-viral medication, which are subject to a Community authorisation through Commission Decision (*central authorisation*). In addition, through technical assistance, EMA supports the network of the Member States on scientific discussions in preparation of *national marketing authorisations* of medicinal products. In the preparation of a scientific assessment of Influenza A (H1N1) 2009 vaccines the EMA is exchanging views with registration authorities in third countries, such as in the US.

While various anti-viral medicines received approval for marketing in the past and are available for treatment of pandemic influenza in the EU, new measures have been concentrated on an accelerated assessment of applications for marketing authorisations of pandemic Influenza A(H1N1) vaccines. Both the EMA and Member States have received or are expecting such applications.

At Community level, the EMA is currently evaluating data and applications for several vaccines. As soon as the EMA provides a positive scientific opinion on each vaccine based

⁶ OJ L 268, 3.10.1998, p. 1.

⁷ [http://www.ecdc.europa.eu/en/healthtopics/Pages/Influenza_A\(H1N1\)_Outbreak.aspx](http://www.ecdc.europa.eu/en/healthtopics/Pages/Influenza_A(H1N1)_Outbreak.aspx)

on a detailed assessment of risks and benefits, the Commission will ensure a swift decision on an authorisation. After authorisation, specific pharmacovigilance monitoring is intended to allow an ongoing assessment of the safety and efficacy of these medicines. In the case of national authorisations, it is up to Member States to decide on any acceleration of the scientific assessment and regulatory procedure.

Human- animal interface

The Commission has also taken action on an additional issue concerning possible infection of pigs with the Pandemic (H1N1) 2009 influenza virus in Europe. This event has already been reported in Canada, Argentina and Australia, probably due to previous human-to-pig transmission. Although in those countries pigs have played no role as an additional source of the virus for humans so far, any possible detection and spread of the pandemic virus amongst pigs in Europe could raise unjustified fears amongst the public.

On 14 July 2009, the Standing Committee on the Food Chain and Animal Health endorsed a guidance document drafted by the Commission on surveillance and control measures for the pandemic virus in pigs⁸, in order to ensure that farmers and veterinary and public health authorities are prepared for any such event and thereby reduce the risk of unjustified panic amongst the public. In addition, recently the Pandemic (H1N1) 2009 virus was detected in turkeys in Chile most likely due to virus transmission from infected humans. The Commission will monitor these developments.

Aviation

Regarding air transport a specific meeting with the Civil Aviation Authorities was organised on 5 May 2009. As a conclusion, it was agreed to activate the network of national contact points for health issues, which allows to exchange and share relevant information on all air transport issues linked to the Pandemic (H1N1) 2009 between EU Member States.

A key question in contingency planning for a possible influenza pandemic is the value of restricting international travel to and from affected countries or regions, or imposing entry or exit screening of passengers at airports. The potential for infectious diseases to spread rapidly through an increasingly well-connected, steadily growing world population was brought into sharp focus during the 2003 epidemic of severe acute respiratory syndrome (SARS). Nevertheless, as it appeared then, the measures on travel restrictions were targeting specific countries in which the epidemic had spread a lot and have a limited effect. Moreover, H1N1 pandemic current situation appears to be very different as it has already spread all over the world. Thus, according to WHO recommendations, travel restrictions were not considered as an appropriate tool in the present situation. Such position was also sent to all aviation authorities by International Civil Aviation Organization (ICAO) on 1 May and confirmed during ICAO's Council meeting on 11 May 2009. In line with this position, no recommendation on travel restriction, including air transport, has been taken at EU level.

Moreover, it was also agreed that according to the evolution of the situation, and taking into account the advice of the relevant health authorities, Member States should take all appropriate measures in the air transport sector. Such measures should be proportionate, non-discriminatory and strictly limited to meet the health risks. In any event, EU coordination of national measures shall continue to be ensured.

⁸ The guidance document is available on the web at:

http://ec.europa.eu/food/animal/diseases/influenzaAH1N1/docs/wd_surveillance_and_control_of_h1n1_in_pigs_rev1_140709_en.pdf

Financial assistance possibilities at EU level

The European Union Solidarity Fund may be called upon by Member States and countries in process of negotiating their accession to the EU⁹ in case of major natural disasters for the reimbursement of certain costs to repair damage. Public health crises and in particular expenditure for buying vaccines do not fall within the scope of the Solidarity Fund.

It should be noted that a Commission initiative to enlarge the scope of the fund to include, among other elements, action in the event of public health crises is pending before the Council without any progress since 2005 (EC proposal COM(2005)108)¹⁰, it would be important to reflect how to move forward on this particular issue. Other structural funds prioritise health investments in infrastructure, hence are less viable in urgent situations.

The accompanying Commission Staff Working Document "Support to third countries to fight Pandemic (H1N1) 2009" addresses the international dimension of the EU response. Should assistance be requested by third countries, the EU could respond as appropriate through its programmes and instruments, including through humanitarian aid.

As far as the Commission is concerned, this financial assistance is expected to be covered by existing financial instruments. If additional important needs rise, the Commission will examine possible available ways of facing these needs

Seventh Framework Programme for Research (FP7)

The Framework Programmes for Research (FP7 and its predecessors FP6 and FP5 have made significant contributions to public health-related research into influenza and to better preparedness for pandemics. Innovative vaccination technologies and adjuvants, surveillance studies on birds and pigs, development of point-of-care diagnostic tools and new antiviral drugs have all been financed by projects under the FPs. In particular, two ongoing FP7 projects are directly relevant to the current pandemic¹¹.

5. INTERNATIONAL COORDINATION

Since the first reports on the outbreak of (H1N1) influenza, the European Commission has been stressing the importance of exchanging information and coordinating measures at international level. The Commission supports the leading role of the WHO in monitoring the pandemic under the International Health Regulations, preparing recommendations and evidence-based guidance, and facilitating support to the poorest countries including providing expertise, supporting capacity building and even procurement of vaccines and antivirals.

As mentioned earlier, the Commission has been also coordinating with the Global Health Security Initiative (GHSI) on public health action and, particularly, exchanging information on public health measures.

The GHSI network is working on issues similar to those identified in the EU context and striving to ensure that they are addressed in a coordinated way across the GHSI countries. The Commission hosted an extraordinary ministerial meeting of the GHSI on 11 September 2009 on issues of common interest related to preparedness for and response to pandemic (H1N1)

⁹ Currently these include only Turkey and Croatia

¹⁰ COM(2005) 108 of 6 April 2005

¹¹ EMPIRE is contributing directly to research into important biological aspects (see http://ec.europa.eu/research/health/infectious-diseases/emerging-epidemics/projects/139_en.html) FLUMODCONT to public health aspects (<http://www.flumodcont.eu/index.php/home>).

For a full overview of all projects please see http://ec.europa.eu/research/health/infectious-diseases/emerging-epidemics/projects_en.html

2009. Mindful of the potential for a more virulent wave of the (H1N1) 2009 influenza virus in the months ahead, the meeting addressed a range of issues critical for an effective response.

During the 14th ministerial meeting of the European Union and the Rio Group (all Latin American countries, the Dominican Republic, Jamaica, Belize, Guyana and Haiti), held in Prague on 13 May 2009, a Joint Declaration on the 'Novel Flu Virus' was adopted. It called for enhancing the ongoing coordination of measures between all competent organisations and bodies.

For the preparation of strategies for the assessment and authorisation of vaccines the European Commission, the ECDC and the EMEA are in close contact with the WHO and via the WHO also with other regulatory authorities worldwide. Furthermore, the Commission and the EMEA concluded bilateral confidentiality arrangements with regulatory agencies of three third countries for the regulatory and scientific collaboration (US, Canada, Japan) which has been experienced a useful mechanism for information exchange in the current pandemic.

6. SOCIAL AND ECONOMIC EFFECTS OF THE PANDEMIC

The World Bank estimates that the measures put in place to slow down the spread of a pandemic, although appropriate, could have a great economic impact. They are said to account for 60% of the total costs. Only 12% would be linked to mortality and 28% to absenteeism and illness. Experience has shown that the economic impact of a health crisis is rarely directly correlated to the medical severity of the virus.

The immediate impact is likely to attract the most public attention. However, depending on the duration and severity of the pandemic, the long-term effect can significantly exceed the short-term costs.

Immediate effects (epidemiological uncertainty)

The most immediate economic impact of a pandemic might arise not from actual death or sickness but from uncoordinated efforts by individuals to avoid becoming infected.

It is anticipated that there could be growing demand for hospitalization and medical treatment, as well as for medicines, including antivirals and vaccines, masks, gloves, antimicrobials and other counter measures. However, limited spare capacity of some service providers could lead to a situation when other health services could be crowded out by those which are pandemic-related.

Apart from healthcare-related developments, people are expected to take additional precautions and to minimise face-to-face interactions in order to avoid infection. In the worst case scenario, this could trigger a decline in demand in some economic and cross-border mobility of people and goods could be hampered.

For the labour market, the main cost is linked to the increased morbidity. This would lead to absenteeism from work, disruption of production processes, shifts to more costly procedures and, eventually, lower productivity. If the psychological impact of the pandemic is especially severe, absenteeism amongst otherwise healthy workers can also be expected.

The Health Council in its Conclusions of 16 December 2008 asked the Commission to take into account the inter-sectoral dimension of preparing for pandemic influenza by reviewing the arrangements covering this area and by updating the Communication from the Commission to the Council and the European Parliament of 28 November 2005 on Pandemic Influenza Preparedness Planning.

The Commission is reflecting on possible on strengthening of inter- and multi-sectoral collaboration, to help mitigate the more general effects of the current pandemic and possible future pandemics.

Long-term effects (economic uncertainty)

The costs related to economic uncertainties associated with pandemics, especially in times of current economic hardship, can slow down fragile economic recovery. For developing countries, the WHO has stressed that all means available will be used to avoid inequities and give developing countries access to vaccines. This would make sure that developing countries do not suffer disproportionately. A strong health system is also necessary. This is why the WHO has called for solidarity to target such structural weaknesses too. On 20 May 2009, the WHO issued a report which stated that 72 countries had been provided with antiviral medicines.

The World Bank supports solidarity with countries that need help to respond efficiently to the pandemic and its effects. Therefore, on 2 June the World Bank approved 'fast-track' status for \$500 million to help countries finance operations to prevent and control outbreaks of pandemic (H1N1) 2009.

Effects on global, regional or national security

The diffusion of the pandemic (H1N1) 2009 may have important implications on global regional and national security, stability and governance. In this respect an EU external policy aimed at strengthening "early warning" capacity in third countries should be seen as a major component of the overall EU Security Strategy and a major EU contribution to better world stability and governance.

7. KEY STRATEGIC STRANDS¹²

Joint procurement of vaccines

During the informal Health Council on 6 July and based on a broad consensus on pursuing joint procurement of vaccine against the pandemic (H1N1) 2009 influenza virus, in particular for Member States which had not yet placed orders, the Swedish Presidency asked the Commission to set up a mechanism to help with joint procurement of vaccines for interested Member States.

Given the stage of development of the pandemic, and the advance purchase orders already concluded by several member states, it is not considered reasonable or efficient at this stage to launch a joint procurement procedure at EU level between interested Member States for vaccine procurement.

The aim should rather be to launch *a bundle of national calls for tender by the interested Member States to be carried out simultaneously or as a whole*. At first sight, taking into account the time pressure (vaccines to be bought in October) this option seems to be the most workable (all contractual documents in place, no issue of conflict of laws) and it could have the most significant impact in ensuring availability of supply of vaccines for target and priority groups in the timeframe available.

¹² Five technical documents have been prepared in parallel to this Communication to set out the key strategic areas. These documents provide an overview of the range of potential actions that can be useful in supporting Member States efforts in responding to the pandemic.

The Commission will support the Member States in their joint procurement efforts and will organise necessary coordination meetings. The Commission is ready to act as facilitator in order to provide advice on the EU legal basis where necessary and support mutual information exchange between Member States having already advance purchase agreements and those having not yet concluded such agreements. For the mid and long term the Commission will continue exploring alternative procedures.

The Commission also encourages, in parallel to the joint procurement initiative, a common approach to cross-border sharing and voluntary sale within the EU. A mechanism to envisage cooperation between Member States in order to address shortages of vaccine in one Member State and high supplies in another country could be envisaged and might be coordinated at EU level. On the basis of the replies received so far by the Commission, some Member States have already included in the contracts that vaccines, which are not used, can be sold to other countries.

Support to third countries to fight Pandemic (H1N1) 2009

The key specific objective of the staff working document on support to third countries is to identify areas and existing EU mechanisms by which the needs of third countries could be supported with the aim of steadily increasing their level of protection in the face of the pandemic (H1N1) 2009, while respecting the principles of country ownership and aid effectiveness. All donor support to the health sector in developing countries has to respect country leadership in strategy design and ownership of the implementation process, as internationally agreed in 2008 in the Accra Agenda for Action, in order to make the international aid effort more effective. It is important to ensure that initiation and concrete help for third countries is carried out in close cooperation with the WHO and, where relevant, with Non-Governmental Organisations (NGOs). A gradual increase of cooperation between ECDC and certain third countries, in particular those falling under the European Neighbourhood Policy, would also help in fighting the pandemic.

The Commission has strongly contributed to global influenza preparedness through its leading role in the global response against Avian Influenza going largely beyond the sole challenge of Avian Influenza, focusing on the sustainable reinforcement of health systems and including general pandemic preparedness. Furthermore, the European Commission is providing funding to a number of low income countries through a range of bilateral measures (projects, health sector budget support, general budget support and regional programmes), so that their national health systems can respond more adequately to the challenge of Pandemic (H1N1) 2009.

The Commission will address the following specific objectives: to closely monitor the situation in third countries, through regular relations with UNSIC, WHO, EU Member states and with other stakeholders, so as to be in a position to confirm in time a potential threat from the pandemic (H1N1) 2009; to identify the actual needs of the countries, for strengthening their preparedness and prevention capacities, but also for coping with acute outbreaks if and when they occur; to conduct EU vaccine procurement in a way so as not to impede access by developing countries to vaccine and other medical goods and to promote increased access taking into account limited resources. In line with the WHO Director-General's call for international solidarity to provide fair and equitable access for all countries to pandemic vaccine when it becomes available, the possibility to reserve for developing countries a share of vaccines ordered by Member States should be seriously considered.

Vaccination strategies

Recognising that the responsibility for developing a vaccination strategy against pandemic (H1N1) 2009 lies with the Member States, the Commission Staff Working Document on

vaccination strategies based on the current scientific evidence and epidemiological trends sets out possible options that Member States might take into account when determining strategies fitting the specific conditions prevailing on their territories. Indeed, based on the broad orientations provided for by the Commission Staff Working Document Member States can develop different vaccination schemes, taking into account epidemiological trends, health service structures and available resources. The statement on target and priority groups for vaccination against pandemic (H1N1) 2009 influenza, agreed by the European Union Health Security Committee on 26 August 2009, provided basis for this document¹³.

The initial limited availability of vaccines, together with the potential need for a large-scale vaccination campaign, poses challenges to healthcare systems and highlights the need for a carefully planned vaccination strategy, taking into account the need to protect vulnerable people, to limit the spread of infection and to maintain essential services in the society. Public confidence, and therefore the success of any vaccination campaign against pandemic (H1N1) 2009, will depend on active and transparent communication on the benefits and the risks of vaccination against pandemic (H1N1) 2009.

Indeed it is important to consider that there is a common interest for each national vaccination scheme to be efficient in order to curb the spread of the virus and to eliminate any "virus reservoir" to prevent further successive reactivations of the pandemic.

Regulatory process for the authorisation of antiviral medicines and vaccines

The EU has prepared itself early for a pandemic through establishing provisions for an accelerated assessment, such as the assessment of new applications for marketing authorisations of pandemic Influenza A (H1N1) vaccines and variations thereof.

The Commission Staff working document provides a comprehensive overview on the key steps and aspects related to the authorisation of anti-viral medicines and vaccines. Specific consideration is given to a description of tailor-made provisions for a fast-track authorisation in a pandemic situation and subsequent pharmacovigilance obligations.

Communication to the public and media on Pandemic (H1N1) 2009

To achieve an adequate uptake of vaccines among risk groups and to deal efficiently with other prevention and vaccination-related problems, public health authorities across Europe will face challenges necessitating a carefully planned communication strategy.

The Staff Working Document on Information to the Public outlines the main issues relating to coordinated communication with the public on pandemic (H1N1) 2009 with a view to delivering targeted and scientifically validated messages for the general public and for specific risk groups. The document identifies possible joint action between the EU Member States and the Commission to develop a coherent European strategy on information and communication.

8. CONCLUSIONS

Pandemic (H1N1) 2009 is a global challenge. In the Commission's view, the EU coordination has worked well so far. This crisis has shown that efficient channels for exchanging information are in place to support good cooperation and coordination of efforts at European level. The international work and collaboration can also be built on to tackle health threats effectively. The benefits are that they ensure coherence and maximise the effectiveness of the

¹³ http://ec.europa.eu/health/ph_threats/com/Influenza/novelflu_en.htm.

national public health response. The Commission will continue to work toward supporting national health authorities to review their preparedness regimes and their response to the pandemic as appropriate.

Inter-sectoral action will remain a key component in tackling pandemic (H1N1) 2009. An important dimension of responses to a pandemic at any level is that they must be multi-sectoral, encompassing services outside the health sector. More needs to be done and the Commission will consider with Member States the need for measures to strengthen inter and multi-sectoral collaboration to ensure business continuity and minimise the disruption of the negative impact of the pandemic.

Depending on the scale and severity of the public health situation, business continuity plans could also identify measures and arrangements to keep critical services working. Establishing continuity plans in relevant areas will be useful to prevent any avoidable, negative economic impact of the influenza pandemic.