COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15.9.2009
SEC(2009) 1192 final

COMMISSION STAFF WORKING DOCUMENT

on support to third countries to fight the Influenza A(H1N1)

accompanying the

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

{COM(2009) 481}
{SEC(2009) 1188}
{SEC(2009) 1189}
{SEC(2009) 1190}
{SEC(2009) 1191}

1. INTRODUCTION

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

On 11 June 2009, the World Health Organisation (WHO) officially declared a pandemic, due to the novel influenza A(H1N1) virus, hereafter called 'pandemic influenza (H1N1) 2009'. This declaration was in full conformity with the WHO global influenza preparedness plan where phase 6, the pandemic phase, is characterized by 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 was a reflection of the spread of the new virus, not the severity of illness caused by it.

This recognition of pandemic (H1N1) 2009 implies that all countries could or would be affected and that a globally concerted response is required to monitor and control the situation. As EU Member States have announced that they are developing extensive plans and are committing significant funds to strengthen their capacities to prevent and/or to mitigate the effects of the pandemic within Europe, the EU cannot ignore the potential consequences for the populations of third countries, in particular developing countries. This is an issue of solidarity and of efficiency in the face of a global crisis.

The current document results from an informal Council of health ministers on 6-7 July where the Commission was requested to continue to prepare for the ongoing pandemic in view of the expected second wave in autumn in the northern hemisphere. In addition to other documents dealing with EU internal issues related to pandemic (H1N1) 2009 response, such as public information, epidemiological surveillance, and a joint mechanism to facilitate procurement of vaccines and antivirals, the Council asked for a special paper on EU support to third countries.

At this current stage of the H1N1 pandemic, we know very little about its actual impact on developing countries, and on its potential development in the short and medium term. Despite recent improvements in local authorities' awareness, surveillance systems and laboratory capacities (mainly as a result of the global response to the Avian Influenza threat) reliable data is lacking and the limited number of reported cases and related deaths does not provide sufficient evidence.

Within the framework of the International Health Regulations (IHR), which came into force in 2008, the international community has mandated the World Health Organisation (WHO) to monitor and analyse the overall situation and, on the basis of the best available evidence, to make proposals for appropriate control measures, as well as ensuring the proper coordination of international support to the most needy countries.

The European Commission has been actively supporting the global response to Avian Influenza politically, technically and financially by setting up of and contributing to a World Bank (WB) trust fund for example. .The Commission has also developed good working relations with the UN senior influenza coordination (UNSIC) and with international organisations such as WHO, World Organisation for Animal Health OIE and WB and built a pool of EC/EU internal expertise and a forum for exchanging information that could be widened to cope with this new pandemic.

2. PURPOSE AND OBJECTIVES

The key specific objective of the current document is to identify areas and 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 influenza (H1N1) 2009, while respecting the principles of country ownership and aid effectiveness.

In particular, the European Commission should address the following specific objectives

- To closely monitor the situation in third countries, through regular relations with the European Centre for Disease Prevention and Control, UNSIC, WHO, EU Member States, partner countries, and with other stakeholders, to be in a position to address 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.

3. LEGAL ASPECTS

According to the objectives of the Community action in the field of public health as set out in Article 152 of the Treaty, the Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health. Community action shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges by promoting research into their causes, their transmission and their prevention, as well as health information and education.

On the other hand, based on Article 177 to 181 of the Treaty, and according to the EU Consensus for Development adopted by the European Union in 2006, the Union commits to the principles of ownership of development strategies by partner countries, and of shared responsibility and accountability between EU and developing countries for their joint efforts. In the Consensus, the EU commits itself to provide more and better aid, and to take action to advance policy coherence for development. These commitments have been confirmed more recently in the Accra Agenda for action on aid effectiveness adopted in September 2008.

4. SITUATION AND NEEDS OF THIRD COUNTRIES

4.1. Developing Countries

From a scientific point of view we now understand a great deal about the transmission and the severity of pandemic influenza (H1N1) 2009 in the richer parts of the globe. This is not the case for developing countries where reliable data is almost completely lacking and where our understanding of the potential impact of the virus is extremely limited. For example, as of the 18th of August, less than 3200 lab-confirmed cases, and 11 deaths had been reported in Africa since the onset of the pandemic, while in the EU/EFTA 40156 cases and 63 deaths had been notified (situation as at 19 August 2009). This difference in reported cases probably reflects more the capacity of diagnosing and reporting the disease than actual differences in occurrence.

Developing countries already suffer from a high disease burden from many endemic infectious diseases. Their capacity to monitor, prevent and react in the case of acute outbreaks of more common infectious diseases (such as meningitis or cholera) is very limited. They are obliged to run their health systems with considerably lower levels of funding than the richer nations. Developing countries will inevitably face difficult choices as to how to put their very limited resources to their optimal use. The international community must therefore offer its support in these situations.

It must be remembered that developing countries are particularly vulnerable to the impact of the present world financial and economic crisis. With fiscal space under pressure, p public social spending, in particular services in the fields of education and health, is increasingly liable to be cut, with evident Millennium Development Goal fallouts.. In the context of the international response to the global financial crisis and in line with commitments undertaken at the G20 London Summit of 2 April 2009, the European Commission has set up an ad hoc mechanism, the Vulnerability FLEX, which is expected to play a role in preserving the level of public social service provision.

Nevertheless, the social impact of the pandemic influenza (H1N1) 2009 serves as a strong reminder that we are still very far from being able to guarantee equal access to even basic health care, and that vastly increased efforts are needed if we are to meet this goal. Of additional concern is the issue of availability and affordability of vaccines against pandemic influenza (H1N1) 2009 in developing countries. At the most basic level there are no agreed protocols concerning who to vaccinate and when vaccination should be carried out. It is essential that WHO, which is the lead negotiator with manufacturers on vaccine production, pricing and procurement, should provide adequate details of current global production capacity and on the potential global needs for vaccine supplies.

4.2. Other third countries

Candidates and potential candidates[1]

In the context of the enlargement policy, the Commission helps legal alignment with the *acquis* in the area of public health in the candidates and potential candidates, and supports and monitors the implementation and effective enforcement of national legislation through various instruments of pre-accession strategy. It also monitors the public health situation in these countries.

Currently, the incidence of the circulation of the virus A(H1N1) appears to be low in the candidates and potential candidates from where data are available. Therefore, the situation as regards the pandemic influenza seems not alarming to date. Measures have been taken by all the countries to prepare themselves for the treatment phase in case the virus starts spreading. Processes for purchasing the necessary vaccines and medication have been initiated, hospitals have been prepared to deal with a possible pandemic, training has been provided for health professionals, measures have been put in place at the airports and ports, public information campaigns in the media and on governmental websites have been launched.

European Neighbourhood Policy partners[2]

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1 Candidates (Croatia, Turkey, the former Yugoslav Republic of Macedonia), potential candidates (Albania, Bosnia and Herzegovina, Kosovo (under UNSCR 1244/99), Montenegro, Serbia).

2 Algeria, Armenia, Azerbaijan, Egypt, Georgia, Israel, Jordan, Lebanon, Morocco, occupied Palestinian Territory, Republic of Moldova, Syria, Tunisia, Ukraine, as well as Belarus and Libya

European Neighbourhood Policy (ENP) partners are already affected by pandemic (H1N1) 2009. The epidemiological and preparedness situation appears to be intermediate between the (potential) candidates and the developing countries. ENP partners continue to face a high burden of infectious diseases in poor and rural populations and in some neighbouring countries the financial resources for health remain insufficient.

5. THE CURRENT ORGANISATION OF THE GLOBAL RESPONSE TO THE PANDEMIC (H1N1) 2009 AND THE ROLE OF THE EUROPEAN COMMISSION

As EU Member States are well prepared for a pandemic within Europe, the EU cannot ignore the potential consequences for the populations of third countries. This is an issue of solidarity and of efficiency in the face of a global crisis.

Fortunately, mechanisms to provide a global response to this potentially highly dangerous situation already exist. Thus, via the **International Health Regulations**, the international community has mandated the **World Health Organisation** (WHO) to monitor and analyse the overall situation and, on the basis of the best available evidence, to make proposals for appropriate control measures, as well as ensuring the proper coordination of international support to the most needy countries. This would include vaccine availability in order to assist developing countries (including through humanitarian aid actors).

The European Commission maintains constant contact with WHO and UNSIC in order to follow the development of the pandemic influenza (H1N1) 2009 and to share information and expertise on the internal EU aspects of the spread of the virus. Based on the coordination mechanisms established for Avian Influenza, regular audio conferences are organised with the USA, Japan, Canada, Australia and the UN system. The Commission also uses these links to pay special attention to the changing situation in developing countries and to promote a concerted and coordinated response.

5.1. In developing countries

Worldwide, developing countries are gradually stepping up their surveillance and response to epidemic and pandemic diseases. Following H5N1 and SARS alerts, and with financial and technical support from a number of EU countries, WHO has greatly increased its capacity (at both global and regional levels) to help countries build their emergency preparedness and response plans. 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.

The European Commission has strongly contributed to global influenza preparedness through its leading role in the global response against Avian Influenza. From the onset of the Avian Influenza crisis, the Commission has adopted a broad-scope approach ("One Health" focusing on cross-sectoral co-operation), going largely beyond the sole challenge of Avian Influenza, focusing on the sustainable reinforcement of health systems and including general pandemic preparedness. Among other actions, the Commission has set up, hosted by the World Bank, the Avian and Human Influenza Facility, a multidonor trust fund to which the Commission brings more than 80% of the funds and to which some EU MS also contribute.

In recent years, new initiatives to prevent and respond to high impact infectious diseases and to prepare for a pandemic have been taken, like for instance the line "Cross-border co-operation in animal and human health in Asia" in the regional strategy for Asia. A regional program on highly pathogenic emerging and re-emerging diseases in Asia is about to be launched (including a grant agreement with WHO).

Also thanks to these efforts, the world is considerably better prepared for the current pandemic. Improvements promoted in developing countries since 2006, like the set up of inter-ministerial structures for pandemic preparedness and coordination, and the design of national pandemic plans, have been essential in the response to pandemic (H1N1) 2009. The contribution of the EC to pandemic preparedness remains active, among others through the programs currently in implementation.

The EU has played an active role in the Geneva-based intergovernmental meeting on pandemic influenza preparedness that took place between November 2007 and May 2009 following the resolution of the World Health Assembly WHA 62/10; the EU currently participates to the consultations led by the WHO Director-General, aiming at reaching an agreement on viral sample sharing and benefits for developing countries, before January 2010.

Finally, the Commission and the successive presidencies of the EU, have been largely instrumental in co-organizing the international ministerial conferences and senior official meetings on avian and pandemic influenza (Beijing 2006, Vienna 2006, Bamako 2006, New Delhi 2007, Sharm-el-Sheikh 2008). The Commission is actively collaborating to the organization of the next international ministerial conference that will take place in Hanoi, Vietnam in April 2010. The current H1N1 pandemic is one of the topics that will be addressed on that occasion.

In addition 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 influenza (H1N1) 2009. Such health systems' strengthening involves the provision of well-trained human resources, the proper maintenance of infrastructure, the provision of essential medicines and diagnostic aids as well as improving the overall governance of the health sector. As well as being essential components of the response to the pandemic influenza (H1N1) 2009, these elements are key for ensuring more equitable treatment of patients whatever their condition.

5.2. In other third countries

Candidates and potential candidates

The Instrument for Pre-Accession Assistance (IPA)[3] is intended to support the necessary political, economic and institutional reforms in the preparations for EU membership. This usually covers support for the adoption or progressive alignment with the public health *acquis*, institution building and cross-border cooperation. Assistance is mobilised with a medium-term effect on the basis of a multi-annual strategic planning process. In exceptional cases, assistance within the existing envelopes could be re-directed and mobilised in a shorter term to help tackle to a certain extent the effects of pandemic A(H1N1).

One example of a possible short-term measure is the Technical Assistance and Information Exchange (TAIEX) instrument. This assistance takes the form of training and know-how transfer events (conferences, seminars, workshops and expert mobilisation) which aim to bring together the experience and knowledge of Member State experts and experts from the EU institutions with a targeted audience in the beneficiary countries. This instrument could be foreseen for some limited and targeted interventions linked for example to awareness raising on pandemic.

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[3] Council Regulation (EC) No 1085/2006.

European Neighbourhood Policy partners

Most of the ENP partners have in recent years improved their influenza preparedness and response capacity. The European Commission's external action has been part of this effort. There is increasing EU-ENP health cooperation and dialogue including on disease surveillance and outbreak control. ENP Action Plans that were agreed with twelve ENP countries include health cooperation objectives including objectives related to communicable diseases surveillance and improved health security. The November 2008 Euro-mediterranean health ministerial opened new opportunities to strengthen health cooperation with Mediterranean partners. Mediterranean ENP countries participate in the EpiSouth Network for communicable diseases control in southern Europe and the Mediterranean, running under the EC public health programme. Several ENP partners expressed interest to increase cooperation with ECDC.

The EU is funding, under European Neighbourhood and Partnership Instrument, health sector budget support operations and major health projects in a range of ENP countries (e.g. Algeria, Egypt, Republic of Moldova, Morocco, Syria, occupied Palestinian Territory). They support the overall strengthening of health systems and contribute to a better diagnosis and treatment of patients, including those affected by pandemic influenza (H1N1) 2009. A number of ENP countries (e.g. Egypt, occupied Palestinian Territory) have benefited from support through the Avian and Human Influenza Facility trust fund.

6. EC APPROACH TO THE GLOBAL DIMENSION OF THE PANDEMIC INFLUENZA (H1N1) 2009 AND THE WAY FORWARD

As part of its North-South solidarity, the European Commission must respond appropriately to the difficulties that developing countries face due to the pandemic influenza H1N1 2009. Furthermore the European Commission should be seen to be responding appropriately to the needs of the developing countries. The response could comprise the following elements:

(1) The Commission confirms its support for the lead role of WHO as the agency responsible for monitoring the evolution of pandemic influenza (H1N1) 2009 world-wide, providing impartial and evidence-based advice on measures to be taken and for coordinating the support of the international community to countries in need. It confirms its support to UNSIC in its coordinating role, inside the UN system and with international partners.

(2) The Commission will make every effort to maintain its support for the strengthening of health systems in developing countries as a priority for EC development cooperation. The strengthening of health systems can only be done in accordance with the needs and development agendas of each individual country and must respect the principles of national ownership and aid effectiveness.

(3) The European Commission humanitarian aid programmes are already sensitised to respond to novel flu through the support they provide to refugees, internally displaced people and victims of natural disasters or conflicts, - groups which are highly vulnerable to pandemic influenza (H1N1) 2009. A task force has been set up in the Directorate-General for Humanitarian Aid has organised internally a close monitoring of the evolution of the pandemic influenza (H1N1) 2009 risk, and to coordinate and adapt regularly the humanitarian response strategy. If the pandemic influenza (H1N1) 2009 intensifies, emergency interventions could be rapidly launched as and where needed by the Directorate-General for Humanitarian Aid.

(4) The Commission will monitor the global effects of EU internal policies and actions, particularly on developing countries. The Commission will encourage the EU to implement the WHO-led support for improved global availability of the means needed to combat the pandemic influenza (H1N1) 2009 threat, including a more equitable access to vaccines when they become available. In line with WHO Director-General 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.

(5) The EU has a major role to play having the largest share of relevant vaccine-production capacity and the greatest share of advance purchase agreements. In this respect, adequate negotiations with producers, including the possibility of generic production, tiered pricing, assigning a share of vaccines and anti-viral medicines for developing countries and other means to render vaccines accessible should be considered as part of the global dimension of the response. Any funds needed should be additional and come separately from the already assigned development cooperation and humanitarian aid funds.

(6) The Commission will closely monitor developments of the pandemic influenza (H1N1) 2009 and, if need be, is ready to propose to member States and the European Parliament to apply additional flexibility in the operation of its programs and financial flows for developing countries. Under the current DG RELEX programming, resources are very limited and there is little if any margin for manoeuvre. In this respect RELEX interventions would need to take place in the framework of the existing commitments and current or programmed resource allocations at country or regional level.

(7) The Commission will monitor the implementation of this response to the pandemic (H1N1) 2009 and draw lessons regarding best practice interventions in case of any future, similar crisis. Such lessons would apply to knowledge generation, research, strengthening of policy and intervention capacities.

(8) The European Commission is considering whether the special inter-service Task Force which has been set up to deal with the external aspects of pandemic influenza H5N1 should have its mandate extended to include the impact of pandemic influenza (H1N1) 2009.

(9) The European Commission will encourage the gradual development of cooperation between ECDC and certain third countries, notably those covered by the European Neighbourhood Policy.

Member States and/or third countries confronted with an emergency that overwhelms their national response capability can, at any time, also activate the Community Mechanism for Civil Protection to pool immediate civil protection and medical assistance that could be available in other Member States.