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SANCO/2010/

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EUROPEAN COMMISSION

Brussels, 18.11.2010
SEC(2010) 1440 final

COMMISSION STAFF WORKING DOCUMENT

**on lessons learnt from the H1N1 pandemic and on health security
in the European Union**

1. INTRODUCTION

The purpose of this document is to report on progress made in recent months and to set out the ongoing and future work of the Commission services in relation to preparation for and management of serious cross-border health threats in the European Union.

The Pandemic H1N1 in 2009 was a reminder of the potential of pandemic influenza to cause widespread illness, death and societal disruption. Although it was less severe than expected, the evaluations carried out by the Commission, emphasized the need to reinforce cooperation between Member States within the EU in the management of the response to a pandemic¹.

Based on these findings the Commission services are committed to addressing the lessons learnt and to improve preparedness and response throughout the European Union in particular by:

- analysing and proposing mechanisms on joint procurement of vaccines and antiviral medication and
- updating the guidance on influenza pandemic preparedness and response planning².

The area of communicable diseases such as pandemic influenza is, however, not the only field where Europe needs to improve preparedness and response. Reinforcing the collaboration at EU level is also required on other serious cross-border health threats whatever the origin of the threat.³

As announced in the 2011 work programme⁴ the Commission services therefore consider starting a revision of the legislation on Communicable diseases and prepare an initiative on prevention and control of other serious cross border threats to health.

This staff working paper is structured along these three elements which are also addressed in the Council conclusions of 13 September 2010 on "Lessons learned from the A/H1N1 pandemic – Health Security in the European Union"⁵.

¹ Member States and /or third countries confronted with an emergency that overwhelms their national response capability can, at any time, activate the Community Mechanism for Civil Protection (Council Decision 2007/779 EC, Euratom establishing a Community Civil Protection Mechanism; [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0779\(01\):EN:NOT](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0779(01):EN:NOT)) to pool immediate civil protection and medical assistance that could be available in other Member States in order to support their response strategies. The Commission also adopted a communication 'Towards a stronger European disaster response: the role of civil protection and humanitarian assistance'. It includes the development of scenarios for the main disaster and the mapping of response capacities, and voluntary pools of assets (COM 2010/600 final of 26/10/2010: http://ec.europa.eu/commission_2010-2014/georgieva/files/themes/european_disaster_response_capacity/final%20text%20EN.pdf).

² Communication from the Commission on pandemic influenza preparedness and response planning in the European Community of 28 November 2005

³ For instance, the EU CBRN Action Plan, adopted in 2009, addresses threats which may derive from the misuse of chemical, biological and radiological–nuclear material.

⁴ COM (2010) 623 Final of 27.10.2010.

⁵ Council of the European Union, Document 12665/10

All three elements are interlinked and are part of a reinforced EU approach to such health-related threats, based on the assessment of the H1N1 pandemic, drawing on the experience with the existing Communicable diseases legislation and the work of the Health Security Committee.

They are based on the EU mandate to act in monitoring, early warning and combating serious cross-border threats to health as enshrined in Article 168 of the Treaty on the Functioning of the European Union.

A. JOINT PROCUREMENT OF VACCINES AND ANTIVIRAL MEDICATION

The 'Assessment Report on EU-wide Pandemic Vaccine Strategies'⁶ and the conclusions of the Belgian Presidency 'Conference on lessons learnt from the A(H1N1) pandemic' identified that the individual procurement of pandemic influenza vaccines and antivirals by Member States during the influenza H1N1 pandemic had weaknesses in terms of equitable access and purchasing power to obtain favourable contractual conditions on price, liability, confidentiality, flexibility to adjust the quantities ordered to actual needs, etc. Therefore, the September 2010 Council conclusions invited the Commission to develop a mechanism for joint procurement of vaccines and antiviral medication which allows Member States, on a voluntary basis, common acquisition of these products or common approaches to contract negotiations with the industry. Discussions in the Health Security Committee on options for possible joint procurement procedures are on-going.

Objectives

The main objectives of the action are to:

- help participating Member States improve their purchasing power and have equitable access to vaccines and antivirals.
- strengthen solidarity between Member States.

Joint procurement between Member States is not a new concept: public authorities have been pooling purchasing since years in sectors such as defence and transport. Any (joint) procurement process should start with a thorough analysis of the needs (what needs to be procured, the quantity, technical specifications, delivery, flexibility) which will determine appropriate procurement procedure(s). The resulting arrangements for future contract(s) need to be settled in advance among the participating contracting authorities in a joint procurement agreement.

Pandemic influenza vaccines and/or antivirals can be procured by a joint call for tender for either a public supply contract or a (multiple) framework contract.

In public supply contracts, all contractual terms need to be specified upfront, which makes this option more suitable for e.g. building a stockpile of antivirals. In contrast, framework contracts merely set out the general terms and the detailed elements of the service (timing, place of delivery, volume per specific requirement...) are defined at a later stage in specific contracts.

⁶ http://ec.europa.eu/health/communicable_diseases/docs/assessment_vaccine_en.pdf

Therefore, (multiple) framework contracts are more suitable for e.g. advance procurement of pandemic influenza vaccines. Flexibility for specific requirements of participating contracting authorities is possible in both contract types by splitting the contract in lots. The Commission services intend to examine the possibility for the Commission to participate in any joint procurement.

Individual procurement does not make use of the above-mentioned potential to improve purchasing power. This was identified as unsatisfactory by a number of Member States during the various discussions on the lessons that could be learned from the management of the influenza H1N1 (2009) pandemic.

The reluctance of vaccine suppliers of bearing full product liability was a major issue for the Member States during the recent pandemic. This is an issue which Member States have indicated should be negotiated as part of a joint procurement exercise, taking account of the fact that in previous national procurement contracts, clauses limiting manufacturers' liability may have contributed to reduce citizens trust in vaccine safety.

Next steps

Joint procurement has the potential to improve national purchasing power and contribute to solidarity between participating contracting authorities. It is however a challenging endeavour, as it requires substantial preparatory work and commitment. The more Member States that participate in the joint procurement exercise, the more impact the exercise will have, both in terms of value added in stronger purchasing power, and in ensuring a wide coverage of the participating countries' target groups.

Work is ongoing in the Health Security Committee on the development of the technical modalities of a possible mechanism for joint procurement.

B. EU PANDEMIC INFLUENZA PREPAREDNESS PLANNING AND RESPONSE

The Council has invited the Commission on a number of occasions to update the 2005 EU guidance on pandemic preparedness and response planning. The European Parliament has also called upon the Commission to take a leading role in the co-ordination of all activities with regard to pandemic preparedness planning.

This call is driven by two objectives: the need to reflect the knowledge and experience gained from the 2009 pandemic H1N1; and the need for the whole society to be prepared for a pandemic in particular by improving business continuity planning in sectors other than health. The update of the 2005 EU level pandemic preparedness planning is also required as a means to feed into the ongoing work in the World Health Organization on the review of the International Health Regulations. It is expected that such a review at the international level will be finalized in the course of 2011. In addition, it should be noted that preparedness for health threats also benefits from improved pandemic preparedness planning.

Objectives

The main objectives of the review are to help Member States:

- improve resilience of the health sector and strengthen preparedness and response across Europe;

- strengthen preparedness and response in other sectors of society and economy and increase interoperability between sectors to be better able to service the health sector;
- increase co-operation and communication between all stakeholders including key international stakeholders.

The review will thus focus on strengthening continued and resilient functioning in the health sector. Proposed actions would cover critical sectors on which the continued and robust functioning of the health sector depends in the event of a pandemic and vice versa. Critical sectors could be those identified in the WHO document on Whole-of-Society Pandemic Readiness⁷ and could include civil protection authorities. These actions would help Member States strengthen the functioning of these sectors, to improve business continuity plans and to develop common models to assess and predict the impact of pandemic.

Next steps

The Commission services are considering the ways to assist Member States in the process of revising national pandemic preparedness plans and improving the state of preparedness and response planning. The following main issues would be covered:

- Member States' regular revision of their national pandemic preparedness plans;
- strengthening of the cooperation of public health authorities with health professionals;
- development of pandemic severity indicators;
- development and/or update of Business Continuity Plans in the health sector and other relevant/related sectors at EU level;
- encouragement of solidarity among key players at EU and international level in areas such as health service provision, sharing of expertise, experience and resources such as medical countermeasures, and further exploiting the possibilities of the Common Emergency Communication and Information System developed within the framework of the Council Decision 2007/779 EC.

C HEALTH SECURITY INITIATIVE -2011

As mentioned in the 2011 Commission work programme, a proposal for the revision of the Decision on communicable diseases and an initiative on prevention and control of serious cross border health threats at EU level will be considered.

Objectives

The main objectives of the initiative would be:

⁷ WHO guidelines for pandemic preparedness and response in the non-health sectors (Geneva, May 2009); <http://www.un-pic.org/web/documents/english/WHO%20WOS%20Pandemic%20Readiness%202009-05-05.pdf>

- (1) Reinforcing the collaboration at EU level on serious cross-border health threats (i.e. whatever the origin of the threat) taking account of existing structures and mechanisms at EU level, which implies:
 - Ensuring coherent risk assessment and risk management for fast evolving threats at EU level by putting in place, where necessary, additional structures and coordination mechanisms;
 - Identifying and covering the gaps in "monitoring, early warning of and combating of serious cross-border threats" from the public health perspective;
 - Strengthening coordination on International Health Regulations implementation, public health emergencies of international concern and capacity building at EU level.

- (2) Revising the communicable diseases legislation (Decision n°2119/98/EC of the European Parliament and the Council⁸ and its implementing Decisions):
 - This review would take account of changes in the field of epidemiological surveillance since the adoption of this legislation, notably the creation of the European centre for Disease Prevention and Control (ECDC). It also corresponds to the need for simplification and consolidation of this legislation after more than a decade.
 - Exploring the possibility of a long-term solution for the Health Security Committee. This Committee of representatives of Member States Health Ministries has proved to be a valuable instrument for coordination of national policies in particular during the H1N1 pandemic. In the framework of the abovementioned initiative, the Commission services will consider and examine the possibility to put the Health Security Committee on a sounder legal footing, taking account of the legal basis available in that purpose in the Treaties, as well as of the missions and powers that could be assigned to the Committee within the limits of such legal basis.

⁸ Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community