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COVER NOTE

from: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 17 September 2009

to: Mr Javier SOLANA, Secretary-General/High Representative

Subject: Commission staff working document on
Joint procurement of vaccine against influenza A(H1N1)
Accompanying document to 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

Delegations will find attached Commission document SEC(2009) 1188 final.

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15.9.2009
SEC(2009) 1188 final

**COMMISSION STAFF WORKING DOCUMENT
on Joint procurement of vaccine against influenza A(H1N1)**

Accompanying document to the

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

Pandemic (H1N1) 2009

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1. INTRODUCTION

In the preparation for an expected increase of infection by influenza A(H1N1) 2009 virus from the autumn onwards, vaccines play an important role. Indeed, vaccination with a pandemic vaccine effective against the influenza A(H1N1) 2009 virus can be considered as one of the most effective public health measures.

As specific vaccines can only be developed once the pandemic influenza strain has been isolated, the vaccine will initially only be available in limited quantities and the demand may initially be higher than the supply. The initial limited amount 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.

A number of Member States have already purchase agreements with the producers and the situation is rapidly evolving. While a number of Member States have already committed to cover the entire population with two doses, other Member States have not started procurement procedures or yet concluded purchase agreement with industry.

In this context of limited number of producers for the vaccine, time constraints for its production and of the need to ensure adequate coverage of priority and target groups of the population, coordination among all actors should be considered as a matter of urgency focusing on identifying and putting in place possible mechanisms to help Member States to protect their citizens against the current pandemic influenza A(H1N1). In addition, such mechanisms will be of relevant added value in preparing the EU to respond in a coordinated way to this health threat.

During the informal Health Council of 6 July and on the basis of a large consensus on pursuing joint procurement of vaccine against influenza A(H1N1) 2009, in particular for those Member States with no current orders in place, the Swedish Presidency proposed asking the Commission to set up a mechanism to help joint procurement of vaccines for interested Member States. This was supported by a majority of Member States.

2. DEFINITION AND ADDED VALUE FOR JOINT PROCUREMENT

'Joint procurement' means combining the procurement actions of two or more contracting authorities. The key defining characteristic is that there normally is only one tender published on behalf of all participating authorities. Joint procurement activities are not new in a number of Member States where the public authorities have been buying together for a number of years; but not all Member States have experience in this area.

There are several benefits for contracting authorities engaging in joint procurement arrangements:

Lower prices – Combining purchasing activities can lead to economies of scale. This is likely to lead to more attractive offers from suppliers. Particularly for small contracting authorities, these advantages can be quite significant.

Administrative cost savings – The total administrative work for the group of authorities involved in preparing and carrying out one rather than several tenders can be substantially

reduced. How much it is reduced will depend on the type of joint procurement arrangement used.

Skills and expertise – Joining the procurement actions of several authorities also enables the pooling of different expertise between the authorities. Smaller authorities in particular can benefit from the capacities of staff in larger authorities.

3. BACKGROUND AND OBJECTIVES

A joint procurement initiative of vaccine against influenza A(H1N1) 2009, in addition to the benefits mentioned above will increase the total number of doses rapidly available to the priority groups in the Member States. This fact will help the national authorities to proceed with the vaccination strategy forecasted at National level. The ad hoc Commission staff working document on 'Vaccination Strategies against Influenza A(H1N1) 2009' covers in detail the issues related to the topic at EU level.

As a follow up of the call from the Swedish presidency and in order to establish the level of interest among Member States, the Commission sent a letter to the Member States asking if they would be interested in participating in joint procurement of vaccines and if so to nominate a representative so that a first contact meeting can be organised soon. Several Member States have already favourably responded to the Commission.

Members of the Health Security Committee (HSC) and the National authorities of the Early Warning and Response System (EWRS) have been informed of the (possible) initiative during the regular meeting on the 14 August. The initiative was acknowledged and it was underlined that the current experience of those Member States who have already signed advanced purchase agreements with the producers could be of added value in helping the initiative.

4. BEING IN LINE WITH THE CURRENT EU AND NATIONAL LEGISLATION

According to the objectives of the Community action in the field of public health as set out in Article 152 of the Treaty, 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. In this case, a joint procurement of the specific vaccine against influenza A(H1N1) will complement the national policy in Member States.

Joint procurement involving several Member States would be in line with the Community law on public procurement in accordance with the national transposition of the European Community Public Procurement Directives. This legal frame provides a basis for the Member States to coordinate their efforts in procurement.

However, potential constraints at the national levels could challenge the procedure as contracting authorities normally have to apply their own national procurement rules and the transposition laws in the Member States are quite diverse as the EC Directives are only coordinating but not harmonising European procurement rules.

Competition rules apply in principle to all economic activities whether carried out by private or public undertakings. It is indeed a settled case law that the notion of "undertaking" for the purposes of EC competition rules can cover any entity engaged in an economic activity, regardless of the legal status of that entity. However, a distinction must be drawn between a situation where the State acts as a mere purchaser in the exercise of its competence as public authority and that where it carries on economic activities of an industrial or commercial nature by offering goods or services on the market¹. The joint procurement of the pandemic vaccine by Member States appears to constitute a measure of public health typically exercised by a public authority and can as such be distinguished from an activity of economic nature to which the application of competition rules of the Treaty may be justified². As a result, it is unlikely that EC competition rules would apply. Only where the Member States or the Commission would consider carrying out activities of an economic nature involving the vaccines at hand, competition rules may become applicable to those activities (e.g., regarding subsequent (re)sale of vaccines, etc...).

5. POTENTIAL ACTIONS FOR 'JOINT PROCUREMENT' OF VACCINE AGAINST INFLUENZA A(H1N1) 2009

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.

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 advanced purchase agreements and those having not yet concluded such agreements.

For the mid and long term the Commission will continue exploring alternative procedures.

The second area for cooperation could be in the sharing of stocks between Member States: During the informal meeting of the EU Health Ministers in Jönköping on 6-7 July 2009, it was suggested that the Commission would facilitate countries that possess vaccines, to make voluntary sales to other countries. In view of the imbalance between a high supply of the vaccine in one Member State and a shortage, or even a lack, of the vaccine in another, a cross-border exchange of vaccines may need to be considered.

¹ Case 118/85 Commission v Italy [1987] ECR 2599, paragraph 7

² Case C-364/92 SAT Fluggesellschaft v Eurocontrol [1994] ECR I-43, paragraph 30 (regarding environmental measures).

In this perspective the Commission 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.

6. OPEN THE POSSIBILITY TO THE CANDIDATES AND POTENTIAL CANDIDATES AND TO THE NEIGHBOURING COUNTRIES – THE INTERNATIONAL DIMENSION

Neighbouring countries and candidates and potential candidates may also be involved in the initiative with Member States. The international dimension is addressed in the specific Commission staff working documents on 'Support to Third Countries to fight the H1N1 influenza'.

In general the EU policy on the issue of support to third countries will include the availability and accessibility of the means needed to combat the pandemic influenza (H1N1) 2009 threat, including a more equitable access to vaccines when they become available, and will be in line with the technical recommendations proposed by the WHO as regards to whom (i.e. at-risk populations, health-care providers, security forces) and when the vaccine should be distributed.

The Commission is working closely with the WHO to assess the global production capacities for these vaccines; to determine which part of this production has been already ordered (advanced purchases) by rich countries, including EU Member States, what will be the demands by the EU Member States on the basis of vaccination strategies implemented; and what will be the requirements of least developed countries. Some vaccine producers have already committed 10% of the production to be reserved for the WHO to distribute to countries in need.