

MEMO

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Framework contracts for pandemic influenza vaccines

Why are Member States and the Commission signing the framework contracts?

During the 2009 influenza pandemic that caused 18,449 deaths, many EU Member States struggled to obtain sufficient quantities of vaccines as quickly as needed and had to accept unfavourable contractual terms. The 2010 Assessment report on EU-wide Pandemic Vaccine Strategies and the Belgian Presidency conference on lessons learned from the A(H1N1) pandemic identified weaknesses related to price, liability and availability of vaccines. The Health Ministers at the Council of December 2010 invited the Commission to develop a joint procurement mechanism for pandemic vaccines.

Which Member States signed the joint procurement of pandemic influenza vaccines today?

Belgium, Croatia, Cyprus, Estonia, France, Germany, Greece, Ireland, Luxembourg, Malta, the Netherlands, Portugal, Slovakia, Slovenia and Spain.

What is the expected value added of this initiative in relation to other situations (e.g. private contracts or contracts just among a few Member States)?

By pooling needs and increasing volumes to be procured, the agreement improves Member States' preparedness for the next flu pandemic, ensures equal treatment, guarantees more balanced prices and shows a high level of solidarity between EU Member States agreeing to share a limited availability of flu vaccines in case of a pandemic. It allows for a greater exchange of best practices and pooling of expertise, and ensures equal access to all participating Member States.

The conditions agreed will guarantee access to a defined part of the production capacity of the company Seqirus for up to 6 years, the total duration of the contract.

The signature of a second contract with another pharmaceutical company is under preparation to maximise the vaccine coverage, according to the specific needs of the participating Member States, and will further improve Member States' preparedness for the next pandemic.

What happens to the non-signatories in case of a pandemic?

The EU joint procurement mechanism is a voluntary mechanism to which all Member States were invited to join. However, for their own reasons, some Member States have decided not to join.

Taking into account the voluntary nature of the joint procurement mechanism, no contingency plans are currently in place with regard to the Member States that have not concluded reservation contracts or advance purchase agreements for pandemic influenza vaccines. However, it is anticipated that vaccine producers will have additional quantities for latecomers, while the Commission will encourage Member States' solidarity in case of a health emergency.

How much time does it take to produce the vaccine?

For the production of a pandemic vaccine, producers are dependent on the availability of the pandemic seed virus strain. This seed virus will be supplied by the World Health Organisation (WHO) reference laboratories. When the manufacturers have received this material, the seed virus has to be made suitable for the production process and this adaptation may take 4-6 weeks depending on the characteristics of the virus strain. If the WHO declares a pandemic, it can be assumed that manufacturers will have already received the necessary seed virus.

The time to produce the actual pandemic vaccine is roughly 12-14 weeks. A critical element will be how the virus performs in the production process and what yield can be obtained. The availability of

the seed virus and the yield obtained in the production process are the two key factors affecting the timelines of the production of pandemic vaccines.

How many EU citizens could potentially benefit from vaccines procured under this contract?

The Member States that signed account for around half of the EU population. As to the specific groups of the population who will receive this vaccination in case of an influenza pandemic, it is the Member States' decision based on their national vaccination plans.

With which company did the Member States and the Commission sign the agreement today?

They signed the framework contract with Seqirus.

What is the subject of the contracts signed with Seqirus?

The subject of the framework contracts is an agreement for the production and supply of pandemic influenza vaccines by the contractor to 30 contracting authorities from 15 Member States of the European Union and to the European Commission in the event of an influenza pandemic. It is concluded for a period of 48 months from its entry into force, with the possibility to be renewed twice for twelve (12) months each. Each participating contracting authority has signed an individual and identical framework contract governed by the applicable law that the parties have designated.

The contractor will reserve a percentage of its weekly manufacturing capacity and assign this percentage solely for the fulfilment of orders placed by the EU contracting authorities. In order for the contractor to maintain its readiness to deliver the reserved number of vaccine doses according to the agreed delivery plan, the contracting authorities will pay an annual preparedness fee. The fee is calculated by multiplying the preparedness fee per dose of vaccine by the number of doses reserved by each contracting authority, as well as the actual price of the doses ordered in the event of a pandemic. The contract provides in detail the conditions related to the ordering and delivery including the penalties in case of delays, liability, cancellation and termination of the contract.

Why was this company chosen to sign the contracts?

The Commission supports Member States' preparation for any future pandemic by having reservation/purchasing contracts in place before outbreaks occur, in line with any legislation already in place. Taking into account the limited production capacity of pandemic influenza vaccines, the Specific Procurement Procedure Steering Committee, comprised of Member States' representatives, decided to procure all available pandemic influenza vaccines with an EU-wide marketing authorisation and invited all companies to submit an offer. Only two companies submitted offers. Negotiations with the second company are still ongoing.

What is the duration of the contract?

The duration of the contract is 48 months with the possibility of renewal twice for twelve (12) months each.

The average time between two consecutive influenza pandemics can be up to 10-15 years, however, the length of the inter-epidemic periods between pandemic influenza outbreaks cannot be predicted. The last pandemic influenza was in 2009 (H1N1pdm09 virus).

What happens if the vaccines are not used within this period?

The product is subject to the packaging and labelling requirements of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, including the expiration of the shelf life of the supplies concerned.

What are the contractor's obligations?

The contractor has to ensure that the production capacity be maintained for the duration of the contract.

What is the cost of the contract?

This information is confidential because it involves intellectual property rights and trade secrets.

Why does this contract only cover pandemic influenza and not the seasonal flu vaccination where the EU is also facing shortages?

This is a Member States' decision. Member States can decide to procure jointly any medical countermeasure including seasonal flu vaccines if they consider it necessary.

What are serious cross-border threats to health?

A serious, cross-border threat to health is a life-threatening or otherwise serious hazard to health from a biological, chemical, environmental or unknown origin. Such threats spread or entail a significant risk of spreading across the national borders of Member States, and may require coordination at EU level in order to ensure a high level of human health protection.

These could include communicable diseases, bio toxins, chemical and environmental events.

What is the Joint Procurement Agreement?

It is a framework laying down common rules for the practical organization of joint procurement procedures with a view to advance the purchase of medical countermeasures, like diagnostic kits and services, laboratory services, medication, vaccines, antivirals-treatments, medical devices and other goods and services, decontamination kits, masks and protective equipment.

How are decisions taken?

All decisions under the framework of the Joint Procurement Mechanism are taken by the Member States through the Steering Committees as provided in the Agreement. The Joint Procurement Agreement (JPA) established a Joint Procurement Agreement Steering Committee (JPASC), composed of representatives of all Member states that have signed the JPA, and that is responsible for steering matters including decisions on the type of the medical countermeasure to be procured. Any JPASC may propose the launch of a procurement procedure and it can start if at least five contracting parties including the Commission vote in favour. Once such a decision has been taken, a Specific Procurement Procedure Steering Committee (SPPS) composed of representatives of the participating Member States to the procurement of that specific countermeasure shall be established. The Steering Committees are chaired by the Commission.

What is the state of play on the joint procurement procedures?

Botulinum anti-toxin was the first procurement procedure successfully concluded in 2016. The joint procurement on pandemic influenza vaccines was signed today. For the future, EU Member States have expressed interest in joint procurement procedures for diphtheria anti-toxin, Tuberculin and BCG vaccines, and Personal Protective Equipment, all of which are currently in the preparatory phase.

What is the legal basis of the initiative?

Article 5 of the Decision 1082/2013/EU on serious cross-border threats to health provides the legal basis for the establishment of the joint mechanism; "The institutions of the Union and any Member States which so desire may engage in a joint procurement procedure [...] with a view to the advance purchase of medical countermeasures for serious cross-border threats to health."