



PHARM 685

PHARMACEUTICAL COMMITTEE
17 March 2015

Subject: The Joint Procurement agreement for medical countermeasures

Agenda item AOBA

State of play

The Joint Procurement Agreement of medical countermeasures (the JPA) has been signed until now by the following Member States: Belgium, Croatia, Czech Republic, Cyprus, Denmark, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Romania, Slovakia, Slovenia, Spain, and United Kingdom. As Italy and Spain did not complete their internal approval processes of the JPA yet, they have observer status in the Joint Procurement Agreement Steering Committee (JPASC).

Austria, Bulgaria, Finland, France, Germany, Ireland and Sweden are progressing towards internal approval of the JPA before signing.

One Member State (Poland) clearly stated that, for the moment, they do not intend to sign the JPA.

Legal basis

The JPA is concluded between the Commission and the participating MS pursuant to the Financial Regulation, it is considered by the Commission as a budgetary implementing measure of Decision *1082/2013/EU on serious cross-border threats to health*¹.

According to Article 5(3), the joint procurement procedure is to be preceded by a Joint Procurement Agreement between the Parties determining the practical arrangements governing that procedure, and the decision-making process with regard to the choice of the procedure, the assessment of the tenders and the award of the contract.

¹ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC; OJ L 293, 5.11.2013, p. 1–15

Scope of the JPA

Serious cross-border threats to health

Article 3(g) of Decision 1082/2013/EU defines a serious cross border threat to health as "a life threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection".

Article 2 of Decision 1082/2013/EU specifies the following categories of serious cross border threats to health:

- a) threats of biological origin, consisting of:
 - (i) communicable diseases;
 - (ii) antimicrobial resistance and healthcare associated infections related to communicable diseases;
 - (iii) biotoxins or other harmful biological agents not related to communicable diseases;
- b) threats of chemical origin;
- c) threats of environmental origin;
- d) threats of unknown origin;
- e) events which may constitute public health emergencies of international concern under the IHR, provided that they fall under one of the categories of threats set out in points (a) to (d).

The Legal Service of the Commission confirmed that all potential medicines, medical devices, other services and goods that could be used to mitigate/treat a life threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads, or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection, can be procured in common under the JPA.

Medical countermeasures

The Legal Service of the Commission confirmed that the term "medical countermeasures" should be interpreted in the light of the aim of the Decision (Article 1(2) of Decision 1082/2013EU) "to support cooperation and coordination between the Member States in order to improve the prevention and control of the spread of severe human diseases across the borders of the Member States, and to combat other serious cross-border threats to health in order to contribute to a high level of public health protection in the Union".

Where medicines, medical products or services can prove necessary to prevent or to control the spread of severe human diseases across the borders of the Member States, or to combat other serious cross-border threats to health, they should be covered by the term "medical countermeasure".

Management of the joint procurement mechanism

As follows from Article 5 of the JPA, the steering of the whole process is ensured by two types of Steering Committees:

- the permanent Joint Procurement Agreement Steering Committee (the JPASC) that is in charge of all the matters relating to the JPA as such. It is composed of one representative of each Contracting Party (Member States and the Commission).
- the Specific Procurement Procedure Steering Committee(s) (the SPPSC) that will be in charge of the matters relating to specific procurement procedures organised under the JPA. A separate SPPSC will be established for each specific procurement procedure; it will be composed of one representative of each Contracting Party (Member States and the Commission) participating in a specific procurement procedure.

Secretariat and Chair of each Steering Committee are provided by the Commission.

Action to be taken:

For information