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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public health  
**Health threats**

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**EXPLANATORY NOTE**  
**ON**  
**THE JOINT PROCUREMENT MECHANISM**

Disclaimer: This is a technical document prepared for the purpose of supporting a discussion on the Joint Procurement Agreement. Any views expressed in this document are purely those of the authors and may not in any circumstances be regarded as stating an official position of the European Commission.

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## **Abbreviations**

JPA – Joint Procurement Agreement to procure medical countermeasures

JPASC – Joint Procurement Agreement Steering Committee

SPPSC – Specific Procurement Procedure Steering Committee

TFEU – Treaty on the Functioning of the European Union

## 1. INTRODUCTION

### 1.1. Background

The 2010 *'Assessment Report on EU-wide Pandemic Vaccine Strategies'*<sup>1</sup> and the Belgian Presidency *'Conference on lessons learnt from the A(H1N1) pandemic'* identified a number of weaknesses in the procurement of pandemic influenza vaccines and antivirals by Member States during the influenza A H1N1 pandemic in relation to price, liability, confidentiality and flexibility to adjust the quantities ordered to actual needs.

The Council in its conclusions of 13 September 2010<sup>2</sup> invited the Commission to develop a mechanism for vaccines and antiviral medication which would allow Member States, on a voluntary basis, common acquisition of these products or common approaches to contract negotiations with the industry, clearly addressing issues such as liability, availability and price of medicinal products as well as confidentiality.

The Council of 7 December 2010<sup>3</sup> approved the "Technical document on a mechanism for joint procurement of pandemic influenza vaccines and antivirals allowing Member States, on a voluntary basis, common acquisition of these products or common approaches to contract negotiations with the industry".

The need to create a mechanism for joint procurement was also expressed by the European Parliament in a resolution of 8 March 2011.

With this background, the Commission took the necessary steps for the preparation of a mechanism for joint procurement of vaccines in the view of a potential future pandemic.

### 1.2. Global approach

Some Member States have participated in joint procurements in other fields previously. For example, common purchase procedures were launched in sectors such as defence or transport.

At EU level, the first joint procurement involving all Member States was set up by DG CLIMA within the framework of the "Joint Procurement Agreement of common auction platforms" dealing with the organisation of the auctioning of CO<sup>2</sup> certificates in each Member State.

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<sup>1</sup> [http://ec.europa.eu/health/communicable\\_diseases/docs/assessment\\_vaccine\\_en.pdf](http://ec.europa.eu/health/communicable_diseases/docs/assessment_vaccine_en.pdf)

<sup>2</sup> Conclusions from the 3032nd General Affairs Council meeting, available at: [http://ec.europa.eu/health/preparedness\\_response/docs/council\\_lessonsh1n1\\_en.pdf](http://ec.europa.eu/health/preparedness_response/docs/council_lessonsh1n1_en.pdf)

<sup>3</sup> [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/lsa/118254.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/118254.pdf)

## 2. THE LEGAL FRAMEWORK

### 2.1. TFEU

Article 168(1) TFEU states that a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.

Article 168(2) TFEU states that Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas covered by the Union action in the field of public health.

Article 168(5) TFEU allows the European Parliament and the Council to adopt, in accordance with the ordinary legislative procedure and after consultation of the European Economic and Social Committee and the Committee of the Regions, "incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health (...)." Such measures may not harmonise the laws and regulations of the Member States.

### 2.2. Decision 1082/2013/EU<sup>4</sup>

On the basis of Article 168(5) TFEU, Decision 1082/2013/EU was adopted. Article 5 of that decision regards joint procurement of medical countermeasures.

Article 5(1) provides that:

*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.*

It should be noted that the joint procurement is to cover not only pandemic influenza vaccines as initially considered, but in fact any "medical countermeasures for serious cross-border threats to health".

The joint procurement is to be conducted pursuant to the third subparagraph of Article 104(1) of the Financial Regulation<sup>5</sup> and Article 133 of the Rules of Application<sup>6</sup>.

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<sup>4</sup> Decision 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)

<sup>5</sup> Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

<sup>6</sup> Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

According to Article 5(2), participation in such procedure shall be open to all Member States until the publication of the call for tender.

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.

### **2.3. Financial Regulation and Rules of Application**

Article 104(1) of the Financial Regulation provides that if a framework contract is necessary for the implementation of a joint action between an institution and one or more Member States, the procurement procedure may be carried out jointly by the institution and the Member States. It further refers to the Rules of Application.

Article 133 of the Rules of Application states that in case of a joint procurement procedure between an institution and Member States the procedural provisions applicable to the institution apply. It further provides that the institution and the Member States have to agree in particular on the practical modalities for the evaluation of the requests for participation or the tenders, the award of the contract, the law applicable to the contract and the competent court for hearing disputes.

The Financial Regulation and the Rules of Application provide a procedural framework for organising procurement procedures under the JPA.

### **2.4. The Joint Procurement Agreement**

The JPA is not an international treaty, in the meaning of the Vienna Convention on the Law of Treaties<sup>7</sup>. The JPA is not a legal act but an agreement.

From the point of view of the Union law, the JPA is intended to implement a provision of a legislative act, namely, Article 5 of Decision 1082/2013/EU.

Article 5 of Decision 1082/2013/EU sets out, generally, imperative rules to be observed in the joint public procurement of medical countermeasures but it does not provide a legal basis.

As the JPA is concluded between the Commission and the participating MS pursuant to the Financial Regulation, the JPA is considered by the Commission as a budgetary implementing measure of Decision 1082/2013/EU.

Execution of the JPA does not involve the exercise of the public law powers related to health policy conferred under Article 168 TFEU. The JPA is an administrative arrangement concerning purchasing, which is within the

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<sup>7</sup> The Vienna Convention on the Law of Treaties is a treaty concerning the international law on treaties between sovereign states. The Convention was adopted on 22 May 1969 and opened for signature on 23 May 1969 by the United Nations

executive functions of the Commission, and thus Article 17 TEU. In such situations the Commission is not acting under its policy making public law powers at all, but is simply performing its executive / management functions.

Member States' public law powers in health matters are absolutely unaffected because the JPA does not create any conferral of public law power at all.

### **3. THE JOINT PROCUREMENT AGREEMENT**

The JPA was signed by the Commission on 20 of June 2015. The Agreement was also signed by the majority of the Member States<sup>8</sup>.

#### **3.1. Voluntary nature (Article 1)**

The JPA enables Member States and the Commission to organise joint procurement procedures with a view of obtaining medical countermeasures. Participation of a Member State – Party to the JPA in any procurement procedure organised pursuant to the JPA remains voluntary and Member States may choose not to participate in a particular procurement procedure.

Joining the JPA does not imply any financial commitment.

Participation in a particular procurement procedure does not prevent Member States from carrying out independent procurement procedures, also when they involve the same medical countermeasures or the same operators.

#### **3.2. Medical countermeasures (Article 2)**

The JPA does not limit the scope of medical countermeasures that can be obtained through joint procurement procedures<sup>9</sup>.

They can include any medicinal products, medical devices, or other goods or services aimed at combating serious cross border threats to health, as referred to in Article 2 of Decision 1082/2013/EU.

#### **3.3. Allocation of medical countermeasures (Article 17)**

The available amounts of medical countermeasures will be allocated among Member States participating in a particular procurement procedure as approved by the SPPSC.

Participating Member States will receive the total quantity of the ordered or reserved measures, but the rate of delivery will depend on the production capacity of the manufacturers and the generally applicable allocation criteria.

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<sup>8</sup> Please see more details regarding the Member States that signed the JPA under the following webpage: [http://ec.europa.eu/health/preparedness\\_response/joint\\_procurement/jpa\\_signature\\_en.htm](http://ec.europa.eu/health/preparedness_response/joint_procurement/jpa_signature_en.htm)

<sup>9</sup> See more on this issue: point 6.1 of this note. In addition, please see more details on the scope of the JPA in the note under the following webpage: [http://ec.europa.eu/health/preparedness\\_response/docs/jpa\\_note\\_scope\\_en.pdf](http://ec.europa.eu/health/preparedness_response/docs/jpa_note_scope_en.pdf)

Article 17(2) of the JPA foresees a possibility of derogation from the generally applicable allocation criteria in problematic situations, such as delivery problems or urgent needs (e.g. in case of a pandemic striking more strongly in one or more Member States).

### **3.4. Abandonment or cancellation from a procurement procedure (Article 24)**

Abandonment and cancellation of a procurement procedure are governed by Article 114 of the Financial Regulation. In particular, before the contract is signed, the procurement can be abandoned or the award procedure can be cancelled for well-founded and duly substantiated grounds, e.g. if the results of the tender are not satisfactory.

Before the contract is awarded, any Contracting Party that has started a joint procurement procedure may individually abandon that procedure for well-founded and duly substantiated grounds.

### **3.5. Donation of medical countermeasures (Article 31)**

Medical countermeasures obtained thorough procurement procedures under the JPA can be donated under the terms of Article 31 of the JPA. In particular, Contracting Parties may express their interest in receiving the donation and the donating Member State has the right to decide on the beneficiary, taking into account the public health needs of all countries (whether Contracting Parties to the JPA or not) and international organisations interested in the donation.

### **3.6. Applicable law and jurisdiction (Articles 41 and 42)**

The JPA is governed by Union law.

Any disputes arising from the JPA are subject to jurisdiction of the Court of Justice of the European Union.

### **3.7. Duration (Article 47)**

The JPA does not have time limits. It will come to an end once it is replaced by another agreement or terminated.

With regard to specific calls for tenders, it follows from Article 122 of the Rules of Application that duration of a framework contract may not exceed the period of four years. The contract can be also be concluded for a shorter period and renewed, until maximum period of four years.

### **3.8. Amendments (Article 46)**

Any Party to the JPA can propose amendments to the JPA.

An amendment to the JPA requires unanimous approval.

### **3.9. Withdrawal from JPA (Article 48)**

A Member State may withdraw from the JPA at any time.

### **3.10. Joining JPA (Article 49)**

Member States that are not parties to the JPA can decide to participate in the JPA at any time.

However, a joining Member State cannot participate in an already on-going procurement procedure. The same is valid for a contract that has would have been signed following a procurement procedure.

### **3.11. Entry into force (Article 51)**

Entry into force of the JPA requires completion of national procedures for the approval of the JPA by one third of the signatory Member States (or notification of the absence of a need for such procedure, depending on the provisions of respective national legislations).

A specific joint procurement procedure can be organised under the JPA only once the JPA has entered into force.

## **4. MANAGEMENT OF THE JOINT PROCUREMENT**

### **4.1. Steering Committees (Articles 5 and 6)**

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 (JPASC) that is in charge of all the matters relating to the JPA as such;
- the Specific Procurement Procedure Steering Committee(s) (SPPSC) that will be in charge of the matters relating to specific procurement procedures organised under the JPA.

Secretariat and Chair of each Steering Committee are provided by the Commission (SANTE C3).

#### *4.1.1. Joint Procurement Agreement Steering Committee (JPASC)*

JPASC is composed of one representative of each Contracting Party (Member States and the Commission), who can be replaced by an alternate. JPASC members and their alternates can be assisted by advisers.

Tasks of JPASC include:

- adoption of the internal rules of procedure;
- a tentative planning of the work for the approval of the specifications for the specific procedures to be organised;
- the type of medical countermeasures to be procured;

- the order of organisation of the specific procedures;
- preparation of amendments to the JPA;
- matters related to non-compliance by a Contracting Party with JPA, disputes between two or more Contracting Parties, or legal proceedings under the joint procurement procedure concerning all Contracting Parties.

#### 4.1.2. *Specific Procurement Procedure Steering Committee (SPPSC)*

SPPSC will be composed of one representative of each Contracting Party (Member States and the Commission) participating in a specific procurement procedure. Each member can be replaced by an alternate. The members and their alternates can be assisted by advisers.

For each specific procurement procedure, a separate SPPSC will be established.

Each SPPSC will be responsible for matters relating to the specific joint procurement procedure, including:

- technical specifications;
- determination and application of the criteria for allocation of medical countermeasures, including temporary deviations from the allocation criteria;
- any legal proceedings under the framework contract.

## 4.2. **Opinions and approvals**

Following the proposal submitted to a Steering Committee as a result of prior consultations, the Committee issues opinions or approvals.

### 4.2.1. *Opinion*

An opinion is not binding on the Commission, but it should be taken into account to the greatest possible extent.

An opinion is to be delivered by a SPPSC in the following situations:

- conduct of any legal proceedings with regard to a framework contract, as laid down in Article 4(3) and (4) of the JPA;
- content of tender documents, as laid down in Article 16(1) of the JPA.

An opinion is adopted by common accord or – if this cannot be achieved - by a simple majority vote.

#### 4.2.2. *Approval*

In majority of the cases, the Commission takes a decision on the basis of an approval expressed by the relevant Steering Committee.

Approval by SPPSC is required, among others, in the following cases:

- appointment of members of evaluation committees (Article 9(3));
- choice of the type of procurement procedure (Article 14);
- choice of the type of framework contract (Article 15(1)(a));
- adoption of contract notice, technical specifications, draft contract and, in case of a competitive dialogue procedure, any descriptive document (Article 16(2));
- criteria for allocation of medical countermeasures (Article 17(1));
- decision on the award of a contract (Article 21(1)).

An approval is delivered by common accord, or – if this cannot be achieved - by a simple majority vote.

### 4.3. **Decision-making process**

#### 4.3.1. *Common accord (Article 7(1))*

If a Steering Committee is required to give an opinion or an approval, the Contracting Parties represented in the relevant committee should act by common accord.

If common accord cannot be reached, members of a Steering Committee will vote.

#### 4.3.2. *Simple majority (Article 7(2))*

It is required when a common accord cannot be achieved for an opinion of a Steering Committee.

A simple majority is a majority (over 50%) of the members present or represented (one vote per Contracting Party).

#### 4.3.3. *Qualified majority (Article 7(2))*

It is required when a common accord cannot be achieved for an approval of a Steering Committee.

With regard to JPASC, it is defined as 55% of the present or represented members, and representing Contracting Parties comprising at least 65% of the total amount of medical countermeasures covered by the joint procurement.

With regard to proposals on matters concerning only SPPSC, it is defined as 55% of the members of SPPSC and representing Contracting Parties comprising at least 65% of the total actual cost, or if the actual cost is not yet known, the estimated cost, of medical countermeasures covered by the participating Contracting Parties.

The amounts of medical countermeasures purchased by a Member State are not necessarily proportional to its weight in terms of population or of GDP. The level of financial commitment of each Contracting Party was thus considered as the most appropriate and objective criterion to determine a qualified majority.

#### 4.3.4. *Special procedure (Article 7(3))*

It applies in a situation where a qualified majority present or represented in favour of a proposal for an approval cannot be reached after the first vote.

In such case, a second vote is organised. The proposal will be considered as approved if it is passed by a simple majority of the members present or represented voting on behalf of Contracting Parties whose participation in the procedure amounts to at least 50% of the total actual cost, or if the actual cost is not yet known, the estimated cost, of medical countermeasures covered by the by the joint procurement procedure or by the Contracting Parties in SPPSC.

If the proposal cannot be passed after the second vote, a third vote is organised. After this vote the proposal is approved unless there is qualified majority against it.

Such mechanism is intended to prevent launched joint procurement procedures from getting stuck or failing on technical points.

The "Commission proposals" as stated in the JPA do not mean that the Commission is making proposals to adopt legislative or regulatory acts. No binding legal acts are being proposed, and the process does not result in the formal "adoption" of anything in a public law sense. These are just "proposals" in the context of a specific ad hoc procedure created by private agreement to do things like: agreeing amongst Parties on the wording of a model contract – executive co-ordination matters.

None of these "proposals" become legal acts or can create rights or obligations for third parties under public law. "Adoption" in this context just means a SPPSC has agreed on something (how to organise a practicality). The SPPSC decision is an internal document and not formal act under public law. So Member States' public law powers in health matters remain absolutely unaffected by decision taken in the frame of both JPASC and SPPSC as such decisions are taken in the frame of a specific ad hoc procedure created by private agreement.

The table below presents the type of procedure used by relevant Steering Committee in relation to the subject matter of the decision to be adopted by the Commission:

<b>OPINION</b>	
<b>ARTICLE</b>	<b>SUBJECT MATTER</b>
4(3) and 4(4)	Conduct of any legal proceedings in relation to a framework contract
16(1)	Content of tender documents
<b>APPROVAL</b>	
4(4)	Decision to institute a legal proceeding against a contractor in relation to a framework contract
9(2)	Adoption of the pro-forma application form for evaluation committees
9(3)	Appointment of members of evaluation committees
13(3)	Timeframe for providing the procurement needs by Contracting Parties
14(1)	Choice of the type of procurement procedure
15(1)(a)	The type of contract to be awarded
15(1)(b)	The duration of the framework contract and the arrangements for its review
16(2)	Adoption of contract notice, tender specifications, draft contract and, in case of a competitive dialogue procedure, of any descriptive document
17(1)	The generally applicable allocation criteria
20(2)	Excluding or declaring unsuccessful candidate or tenderer
21(1)	Award decision
22(2)	Approval of a contract (only in cases where it differs substantially from the approved draft contract)
22(5)	Authorising the Commission to sign a framework contract on behalf of participating Contracting Parties (in cases of urgency)
24(1) (simple majority)	Collective abandonment of the joint procurement procedure before the award of the contract or collective cancellation of the award procedure before signature of the contract
25(2)	Adoption of the list of candidates invited to negotiate (in case of a negotiated procedure without prior publication of a contract notice in the OJ)
25(4)	Elimination of tenderers in a negotiated procedure following publication of a contract notice in the OJ
26(3)	Exclusion of candidates in a competitive dialogue procedure
26(5)	Notification to the candidates that the dialogues are concluded and invitation to submit their final tenders on the basis of solutions presented and specified during the dialogue (in competitive dialogue)
37(4)	Handling instructions applicable to information or documents handled within the opening or evaluation committees and security measures applicable to meetings of these committees.
<b>SPPSC DECISION (UNANIMITY)</b>	
17(2)	Temporary derogation from generally applicable allocation criteria
<b>JPASC DECISION (UNANIMITY)</b>	
46 second subp	Preparation of amendments to the JPA and its Annexes

## **5. SPECIFIC PROCUREMENT PROCEDURES**

### **5.1. Issues to be decided before publication of a contract notice**

#### *5.1.1. Identification of the Member States needs*

Article 13 (3) of the JPA provides that: "Any Contracting Party that has expressed its interest in participating in the joint procurement procedure shall detail its procurement needs to the Commission within a timeframe specified by the Commission after approval of the SPPSC, in accordance with Article 7."

### 5.1.2. Type of procedure

As stated in Article 14(1) of the JPA, following the start of a procurement procedure, it is up to the SPPSC to decide on the type of procurement procedure. The type of procurement procedure shall be specified in the contract notice.

It must be decided whether an open procedure or whether a restricted procedure with a pre-selection of the economic operators (e.g. on the basis of their technical capacity) should be used. The other procedures that could be used are a negotiated procedure or a competitive dialog.

As stated in Article 12(1) of the JPA, the Commission ensures the overall preparation and organisation of the joint procurement procedure.

#### 5.1.2.1. Open procedure

Open procedure is an ordinary procedure that can be used for any public procurement contract.

As specified in Article 127(2) of the Rules of Application "*procurement procedures are open where all interested economic operators may submit a tender*".

#### 5.1.2.2. Restricted procedure

As an alternative to the open procedure, the restricted procedure can be used for any public contract.

The main difference with an open procedure is that in a restricted procedure all interested economic operators may ask to participate nevertheless, only the economic operators fulfilling the selection criteria and invited may submit a tender for evaluation.

#### 5.1.2.3. Negotiated procedure

Specific provisions on negotiated procedure are laid down in Article 25 of the JPA.

In this procedure, after approval by the SPPSC of the shortlist of candidates drafted by the Commission only these shortlisted candidates will be invited to negotiate.

The negotiations shall be carried out, on the basis of pre-announced criteria provided for in the tender specifications.

#### 5.1.2.4. Competitive dialogue

Specific provisions on competitive dialogue are laid down in Article 26 of the JPA.

Typically, this type of the procedure is used in exceptional circumstances of the particularly complex contracts.

*"A contract is considered to be particularly complex where the contracting authority is not objectively able to define the technical means capable of satisfying the needs or objectives or able to specify the legal or financial make-up of the project"* (Article 132 of the Rules of Application).

### 5.1.3. *Type of contract*

#### 5.1.3.1. Direct contract (public supply contract)

A public supply contract contains all details necessary to implement it, including, and in opposition to the framework contract, time of delivery and the quantity of goods/services to be delivered.

#### 5.1.3.2. Framework contract

The framework contract is used in case when the exact time and the quantity of goods to be delivered cannot be defined in advance.

A framework contract is implemented through specific contracts.

#### 5.1.3.3. Specific contract

A specific contract is a contract concluded on the basis of a framework contract between individual Contracting Party and an economic operator that is the party to this framework contract.

Contracting Parties concerned by a framework contract may award and sign specific contracts up to the number of medical countermeasures they have reserved under the framework contract (Article 27(2) of the JPA).

### 5.1.4. *Technical specifications*

The Commission will finalise the specifications on the basis of all elements gathered during the preparation phase.

One or several formal meetings of the SPPSC with only the interested participating Member States, might have to be organised to formally approve the specifications.

#### 5.1.4.1. Technical specifications

Technical specifications define what products will be procured. Both quality and price should be determined.

*Technical specifications shall define the characteristics of a product, with regard to the purpose for which they are intended (Article 139 RoA).*

#### 5.1.4.2. Definition of lots

Contracts, for which combined value is such that few of the economic operators could provide similar products or services all in their entirety, should be split into lots in order to allow any interested economic operator able to provide similar products or services to tender.

#### 5.1.4.3. Estimated value of the contract

The estimate value of the contract should be fixed before the contract notice is sent or, if there is no such publication, before the launch of the procurement procedure by contracting authority.

The total value of framework contracts (maximum ceiling) is calculated on the basis of the maximum value of all the contracts envisaged during the total maximum lifetime of the framework contract.

#### 5.1.4.4. Exclusion criteria

The purpose of the exclusion criteria is to determine whether an operator is qualified to participate in the tendering procedure.

The criteria which should be applied are set out in Articles 106<sup>10</sup> and 107 of the Financial Regulation.

#### 5.1.4.5. Selection criteria

The purpose of the selection criteria is to determine whether a tenderer has financial, economic, technical and professional capacity necessary to carry out the work.

The selection criteria to be used are set out in Article 146 of the Rules of Application.

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<sup>10</sup> As stated in Article 106 of the Financial Regulation candidates or tenderers shall be excluded from participation in procurement procedures if, ea. they are bankrupt or being wound up, they or persons having powers of representation, decision making have been convicted of an offence concerning their professional conduct by a judgment of a competent authority of a MS, they are not in compliance with their obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed (...).

#### 5.1.4.6. Award criteria

The purpose of the award criteria is to choose the best tender out of those submitted by tenderers which are not excluded and meet the selection criteria.

As specified in Article 110 (2) of the Financial Regulation contracts shall be awarded by the automatic award procedure<sup>11</sup> or by the best-value-for-money procedure<sup>12</sup>.

#### 5.1.4.7. Formula for weighting of technical and financial criteria

The formula used to rank tenders and to calculate which tender offers the best value for money should combine the quality mark and the price, expressed in the form of indices.

The method used must be indicated in the tender documents and must remain unchanged during the whole procedure.

Two formulae are commonly used:

- method with no weighting between quality and price):

Score for tender X = cheapest price/price for tender X\*total quality score (out of 100) for all criteria for tender X

- method applying a weighting for price in absolute values (e.g. 50/50 or 70/30):

Score for tender X = cheapest price/price for tender X\*price weighting (in absolute value) + total quality score (out of 100) for all award criteria of tender X/100\* quality criteria weighting (in absolute value)

or if weightings are expressed in percentage (e.g. 50%/50% or 70%/30%) the formulae is the following:

Score for tender X = cheapest price/price for tender X\*100\* price weighting (in %) + total quality score (out of 100) for all award criteria of tender X\* quality criteria weighting (in %).

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<sup>11</sup> In the automatic award procedure the contract is awarded to the lowest tender that satisfies the technical specifications.

<sup>12</sup> By using this option the contract is awarded to the tender offering the best value for money.

## **5.2. Steps before awarding of the market**

### *5.2.1. Publication of the contract notice*

Article 18 of the JPA clarifies that after the tender documents have been prepared the Commission shall publish a contract notice in the Official Journal of the EU.

The tender documents should be made available to economic operators by Commission on request.

Timing and organisation of the public opening sessions of the received tenders has to be described in the contract notice.

The publication of the contract notice requires the setting up of a structure to receive and deal with questions that might be asked by potential tenderers.

### *5.2.2. Opening of the received tenders*

Received tenders shall be opened by an opening committee made up of persons representing the Commission. Opening of received tenders is public.

As specified in Article 19 (2) of the JPA any Contracting Party may request the Commission to allow one of its representatives to observe the opening of tenders. Nevertheless, the observers shall neither participate in the deliberations of the opening committee nor make known any views to members of that committee (Article 19(3) of the JPA).

### *5.2.3. Evaluation of the received tenders*

Evaluation of the requests to participate or tenders is done by an evaluation committee appointed by the Commission (Article 8 of the JPA).

For organisational and confidentiality reasons it is not foreseen to have one representative of each participating Member States as a member of the evaluation committees.

Participation to the evaluation committees will be restricted to a limited number of people acting as independent evaluators who will provide an opinion to the SPPSC as to the award of the market.

Considering complexity of the tender, and the potential for receiving numerous replies, organisation of the evaluation committees meetings will require extensive coordination and the need to put in place strong measures to ensure proper confidentiality of the proceedings.

### **5.3. Award of the contract**

#### *5.3.1. Award decision*

The award decision shall be adopted by the Commission on its own account and on behalf of the participating Member States after approval by the SPPSC (Article 21 of the JPA). Therefore, a formal meeting of the concerned SPPSC will have to be organised to formally award the market.

#### *5.3.2. Formal information on the award of the contracts*

Once the award decision will have been confirmed by SPPSC, it will have to be notified to tenderers which will have 14 calendar days to request further information on the reasons for not having been awarded the market.

The award decision shall be notified simultaneously to all successful and unsuccessful tenderers or candidates (Article 21 paragraph 3 of the JPA).

#### *5.3.3. Signature of the contracts*

The participating Contracting Parties sign a contract after the adoption of an award decision (Article 22 paragraph 1 of the JPA).

Formal signature of the contract can only occur after a 14 calendar days' standstill period. The contract will enter into force once it will have been signed by the contractor and all concerned Contracting Parties (Article 22 (4) JPA).

## **6. MEDICAL COUNTERMEASURES TO BE PROCURED THROUGH THE JPA**

### **6.1. Scope of medical countermeasures**

#### *6.1.1. Serious cross border threats to health*

According to Article 5 of Decision 1082/2013/EU, joint procurement procedures may be initiated "with a view to the advance purchase of medical countermeasures for serious cross-border threats to health"

The term "serious cross-border threats to health" is defined in Article 3 point g) of Decision 1082/2013/EU 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."

#### *6.1.2. Medical countermeasures*

Article 2 of the JPA provides that medical countermeasures are any medicines, medical devices, other goods or services that are aimed at

combating serious cross-border threats to health, as referred to in Decision 1082/2013/EU.

The term "medical countermeasure" is not defined in Decision 1082/2013/EU.

It should be interpreted in the light of the aim of the Decision which is "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". Any other interpretation, by which certain medicines, medical products or medical services would not be comprised in the definition although cooperation and coordination in their regard between Member States could be required to combat serious cross-border threats to health, would not be compatible with the aim of Decision 1082/2013/EU.

Therefore, 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.

## **6.2. Potential specific procurements – examples**

The joint procurement mechanism can be used for other medical countermeasures than pandemic vaccines.

One can already foresee that this will be done for very different medical countermeasures by very different groups of Member State.

### *6.2.1. Essential medicines for rare infectious diseases*

In Europe, no formal mechanism exists to specifically address shortages of essential medicines for rare infectious diseases, except for smallpox and yellow fever vaccines through the World Health Organization (WHO). Although many Member States have small stockpiles, few have sufficient to cope with larger demand and no stockpiling institution within the European region has procedures in place to assist other Member States should a need arise. Furthermore, several Member States have difficulties in identifying manufacturers for the procurement of some products such as diphtheria antitoxin.

Examples of medicines for which such problems are encountered are:

- Botulism (immune globulin, adult & paediatric)
- Rabies (vaccine and immune globulin)

- Anthrax (vaccine and immune globulin)
- Diphtheria (antitoxin)
- Hepatitis B (immune globulin)
- Orthopox (ST-246)
- Polio (OPV)
- Various antidotes and anti-venoms.

The essential medicines for above rare infectious diseases are existing products that could be procured through a joint procurement provided operational aspects for exchanging the medicines, compensation modalities, regulatory aspects, and liability issues are tackled correctly.

This possibility has been specifically addressed after several presentations of the state of play of the project where public health specialists from the Member States were present.

#### 6.2.2. *Anti-retrovirals for HIV/AIDS and medicines to treat co-infections*

HIV/AIDS is on the list of diseases covered by the EU network for the epidemiological surveillance and control of communicable diseases and thereby in the remit of the Decision 1082/2013/EU.

During consultations in preparation of the 'Action Plan on HIV/AIDS in the EU and neighbouring countries: 2014-2016' the HIV/AIDS Civil Society Forum and selected members of the Think Tank on HIV/AIDS identified joint procurement of anti-retroviral medicines for HIV as a potential measure to increase access to medicines. In addition it was also suggested to explore the potential to procure medicines for common HIV co-infections such as viral hepatitis and tuberculosis.

#### 6.2.3. *Reference laboratories services*

The EU Human Pathogen Reference Laboratories Options Project [EURLOP] identified a series of toxins and communicable diseases for which it is needed to invest on EU level in pan-EU laboratory(ies).

The aim would be to provide specific EU-level services required to mitigate existing weaknesses.

They namely are the following: *Anthrax, Avian Influenza, Brucellosis, Coxiella (Q Fever), Influenza, Plague, SARS, Smallpox, Tularaemia, VHF, AMR, Novel pathogens, Diphtheria, HIV/AIDS, Malaria, Polio, Rabies, vCJD, West Nile Virus, Middle East Respiratory Syndrome coronavirus (MERS-CoV).*

If such pan-EU services could be properly identified and described in sufficient details to allow for the launch of a call for tender, a joint procurement of such services could be organised by using the JPA.

Common definition of services as well as common approach to its delivery would, e.a. create economies of scale and facilitate spreading of common best practices.

#### 6.2.4. *Seasonal flu vaccines*

The EU Council in its Recommendation on ‘seasonal influenza vaccination’<sup>13</sup>, adopted on 22 December 2009 calls on Member States to take action to mitigate the impact of seasonal influenza through national, regional or local action plans or policies as well as by improving seasonal influenza vaccination coverage with the aim of reaching preferably by the 2014-15 winter season, a vaccination coverage rate of 75 per cent for ‘older age groups’.

The reaching of these targets has also to be seen in the light of the current financial and economic crisis and severe budgetary constraints in most EU Member States. In this context, immunisation has to be recognised as an important cost-efficient or even cost-saving means to prevent diseases rather than to treat them, and thus improve citizen's health.

In such conditions it may be useful to use the joint procurement mechanism for the common purchase of the seasonal influenza vaccines.

## 7. THE IMPLEMENTATION OF THE JPA – FIRST JOINT PROCUREMENT PROCEDURES

Following the needs expressed by the Member States the first joint procurement procedure is being organised for the supply, storage and dispatching of personal protective equipment (PPE) for healthcare workers (HCWs) who might need to deal with infectious diseases of high consequence (IDHCs) in European healthcare settings.

In parallel, the Commission is working on the joint procurement of vaccines in the frame of a future pandemic.

In this regard, on 29-30 April 2015 a workshop on the joint procurement of pandemic vaccines has been organised<sup>14</sup> with the objective to ensure that all stakeholders involved in the process of this joint procurement have an as complete and transparent as possible understanding of all aspects that will significantly influence the procedure.

At the workshop several issues related to the procurement of pandemic vaccines were identified for which the decisions must be taken by the Member States before the call for tender can be published.

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<sup>13</sup> 2009/1019/EU

<sup>14</sup> The detailed information related to the workshop is available under the following webpage: [http://ec.europa.eu/health/preparedness\\_response/events/ev20150429\\_en.htm#fragment0](http://ec.europa.eu/health/preparedness_response/events/ev20150429_en.htm#fragment0)

The most outstanding issues to be discussed will relate to: types of vaccines, type of procedure, regulatory aspects related to the type of approval of the vaccines to be procured, packaging, liability for side effects; preparedness fee, key performance indicators, security of supply, as well as triggering of the switch from seasonal to pandemic vaccine production.