



EUROPEAN  
COMMISSION

Brussels, 10.4.2014  
C(2014) 2258 final

**COMMISSION DECISION**

**of 10.4.2014**

**on approval of the Joint Procurement Agreement to procure medical countermeasures  
pursuant to Decision 1082/2013/EU**

(Text with EEA relevance)

## COMMISSION DECISION

of 10.4.2014

### on approval of the Joint Procurement Agreement to procure medical countermeasures pursuant to Decision 1082/2013/EU

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 2119/98/EC<sup>1</sup>, and in particular Article 5(3) thereof,

Whereas:

- (1) The Council in its Conclusions of 13 September 2010 and the European Parliament in its Resolution of 8 March 2011 stressed the need to introduce a common procedure for the joint procurement of medical countermeasures, and in particular of pandemic vaccines, to allow Member States, on a voluntary basis, to benefit from such group purchases.
- (2) In order to be better prepared to deal with serious cross-border threats to health, Article 5 (1) of Decision 1082/2013/EU provides that Union institutions and Member States may engage in joint procedures for the procurement of medical countermeasures.
- (3) The joint procurement of medical countermeasures is considered to strengthen purchasing power allowing for better contractual terms and economies of scale.
- (4) In addition, joint procurement strengthens solidarity by ensuring that participating Member States are afforded equitable access to medical countermeasures. Regarding pandemic influenza vaccines, joint procurement strongly reinforces pandemic preparedness by putting in place advance purchase agreements with pandemic influenza vaccine suppliers.
- (5) In addition, the joint procurement procedure should comply with conditions laid down in Article 5(2) of Decision 1082/2013/EU.
- (6) Pursuant to Article 133 of Commission Delegated Regulation (EU) No 1268/2012 the Commission and the Member States have to agree in particular upon 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. This provision is reflected in Article 5 (3) of Decision 1082/2013/EU which states that the joint procurement procedure shall 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.

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<sup>1</sup> OJ L 293, 5.11.2013, p. 1.

- (7) The Joint Procurement Agreement shall enter into force 14 days following the day on which (i) the Commission has received a signed duplicate of this Agreement from each Contracting Party in all authentic linguistic versions, (ii) the Commission has signed a duplicate in the same authentic linguistic versions, and (iii) one third of all Contracting parties have submitted to the Commission the Confirmation of completion of national procedures for the approval of the JPA or the absence of a need for such procedures.
- (8) The Joint Procurement Agreement is to be signed by the Commission and the participating Member States in 15 different authentic linguistic versions.

HAS DECIDED AS FOLLOWS:

*Article 1*

1. The Commission approves the model Joint Procurement Agreement in the Annex.
2. The Commission authorises the Director-General of the Directorate-General for Health and Consumers to sign all authentic linguistic versions of the Agreement referred to in paragraph 1 on behalf of the Commission.

*Article 2*

1. The Joint Procurement Agreement as concluded by the Commission and the Contracting Parties shall be published in the Official Journal following its entry into force.
2. The authentic linguistic versions of the Joint Procurement Agreement shall be Spanish, Czech, Danish, German, Greek, English, French, Croatian, Italian, Lithuanian, Hungarian, Dutch, Portuguese, Slovak and Slovenian.

Done at Brussels, 10.4.2014

*For the Commission*

*Tonio Borg*  
*Member of the Commission*



EUROPEAN  
COMMISSION

Brussels, 10.4.2014  
C(2014) 2258 final

ANNEX 1

**ANNEX**

**to the  
COMMISSION DECISION**

**on approval of the Joint Procurement Agreement to procure medical countermeasures  
pursuant to Decision 1082/2013/EU**

# JOINT PROCUREMENT AGREEMENT TO PROCURE MEDICAL COUNTERMEASURES

This Joint Procurement Agreement (the "Agreement") is made and entered into force on the [day] of [month], [year] by and between the following Contracting Parties:

the European Commission (the "Commission"), which is represented for the purposes of this Agreement by the Director-General of the Directorate-General for Health and Consumers;  
*Name to be inserted at the moment of signature*

and

the following Member States of the European Union:

1) [Member State];

2)

## PREAMBLE

WHEREAS:

- (1) The second subparagraph of Article 168(1) of the Treaty on the Functioning of the European Union (the "Treaty") provides that "Union action, which shall complement national policies, shall be directed towards improving public health, preventing [...] diseases [...]. Such action shall cover [...] combating serious cross-border threats to health".
- (2) Cross-border threats such as pandemic influenza can be combated through vaccination, preventing potentially severe disease and even death.
- (3) In its Conclusions of 13 September 2010<sup>1</sup>, the Council invited the Commission to report on and develop a mechanism for the joint procurement of vaccines and antiviral medication which would allow Member States, on a voluntary basis, to adopt common approaches to the negotiation of contracts with the industry, that would clearly address issues such as liability, availability and the price of medicinal products as well as confidentiality.
- (4) At the meeting of the Employment, Social Policy, Health and Consumer Affairs Council of 6 and 7 December 2010<sup>2</sup>, a large majority of Member States agreed that the most suitable means of carrying out joint procurement procedures for pandemic vaccines would be to develop framework contracts that Member States may enter into on a voluntary basis.

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<sup>1</sup> <http://register.consilium.europa.eu/pdf/en/10/st13/st13420-re01.en10.pdf>

<sup>2</sup> [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/lisa/118254.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/118254.pdf)

- (5) Article 5(1) of Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013<sup>3</sup> extended this approach beyond vaccines and antivirals against pandemic influenza. Pursuant to that Article, institutions of the Union and Member States may engage in a joint procurement procedure with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.
- (6) It is expected that joint procurement will strengthen the Contracting Parties' purchasing power and ensure equitable access to medical countermeasures against serious cross-border threats to health
- (7) The conclusion of the Joint Procurement Agreement does not entail any obligation on the Contracting Parties to participate subsequently in procurement procedures launched to acquire the specific medical countermeasure on the basis of that Agreement.
- (8) For the purpose of procuring medical countermeasures against serious cross-border threats to health, the Contracting Parties have decided to engage in a joint action, within the meaning of the third subparagraph of Article 104(1) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council<sup>4</sup>.
- (9) The Contracting Parties intend to pursue the joint action, through the award of contracts for the purchase of medical countermeasures against serious cross-border threats to health following one or more joint procurement procedure within the meaning of Commission Delegated Regulation (EU) No 1268/2012<sup>5</sup>, as provided for in Article 5 of Decision No 1082/2013/EU.
- (10) Nothing in this Agreement shall affect the rights and obligations of the Member States and of the Commission under the Treaties, and the achievement of the objectives of the European Union, in particular in the field of public health,

## THE CONTRACTING PARTIES HAVE AGREED

on the terms below including the following Annexes:

**Annex I** – Declaration of absence of conflict of interest and protection of confidentiality to be given by member(s) of the evaluation committee(s) as referred to in Article 37(5)

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<sup>3</sup> 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).

<sup>4</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>5</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).

- Annex II** – Confirmation of completion of national procedures for the approval of this Agreement or the absence of a need for such procedures as referred to in Article 51(4)
- Annex III** – Agreement on participation in the work of the Joint Procurement Agreement Steering Committee as an observer as referred to in the first paragraph of Article 52
- Annex IV** – List of authentic linguistic versions of this Agreement referred to in Article 51(1)

## Title I

### GENERAL PROVISIONS

#### Article 1

##### **Subject matter**

1. This Agreement provides for the possibility of Contracting Parties to acquire medical countermeasures through the award of contracts on the basis of a joint procurement procedure.
2. This Agreement lays down the practical modalities governing the joint procurement procedure in accordance with the third paragraph of Article 133 of the Rules of Application.
3. This Agreement also covers ancillary matters such as:
  - (i) the management of the framework contracts
  - (ii) the conduct of any legal proceedings arising from the joint procurement procedure or the framework contracts, or from a failure to comply with this Agreement; and
  - (iii) the amicable settlement of any disagreements between the Contracting Parties.
4. A person who is not a party to this Agreement shall not be entitled to enforce or enjoy any rights or benefits of any term of this Agreement.
5. This Agreement is without prejudice to the right of the Contracting Parties to carry out procurement procedures outside this Agreement, even where such procedures involve the procurement of medical countermeasures which form the subject of a joint procurement procedure or a framework contract or involve economic operators or contractors who are tendering for, or have signed, a framework contract pursuant to a joint procurement procedure under this Agreement.

#### Article 2

##### **Definitions**

1. All terms in this Agreement derived from or defined in the Financial Regulation or the Rules of Application shall have the same meaning as under those acts.

For the purposes of this Agreement:

- (a) “medical countermeasures” means any medicines, medical devices, other goods or services that are aimed at combating serious cross-border threats to health, as referred to in Decision No 1082/2013/EU.
- (b) “Treaty” means the Treaty on the Functioning of the European Union;



- (c) "framework contract" means a framework contract, referred to in Article 101(2) of the Financial Regulation and Articles 121 and 122 of the Rules of Application, resulting from a joint procurement procedure conducted pursuant to this Agreement and signed by a contractor and one or more Contracting Party;
- (d) "Contracting Party" means a party that has signed this Agreement;
- (e) "economic operator" means any natural or legal person or public entity which offers medical countermeasures on the market;
- (f) "contractor" means a natural or legal person with whom a procurement contract has been concluded following a procurement procedure conducted pursuant to this Agreement;
- (g) "Financial Regulation" means Regulation No 966/2012 (EU, Euratom) 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;
- (h) "Rules of Application" means 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;
- (i) "direct contract" means a public contract, as referred to in Article 101(1) of Financial Regulation, resulting from a joint procurement procedure conducted pursuant to this Agreement and signed by a contractor and one or more Contracting Party(ies);
- (j) "specific contract" means a specific contract as referred to in Article 122 of the Rules of Application, concluded between one Contracting Party and a contractor on the basis of a framework contract;
- (k) "participating Contracting Party" means a Contracting Party participating in a joint procurement procedure for a specific medical countermeasure conducted pursuant to this Agreement;
- (l) "Steering Committees" shall mean the Joint Procurement Agreement Steering Committee and one or more Specific Procurement Procedure Steering Committee
- (m) "staff" means any person working for a Contracting Party;
- (n) "handling" information or documents means generating, processing, storing, transmitting or destroying information or documents;

- (o) "persons working in connection with this Agreement" means any person working for a Contracting Party in connection with this Agreement regardless of whether or not they are employed by that Contracting Party;
- (p) "Court of Justice" means Court of Justice of the European Union;
- (q) "third party" means any natural or legal person, public entity or group thereof that is not a signatory to this Agreement.

### Article 3

#### **Rules governing the joint procurement procedure**

1. The first paragraph of Article 133 of the Rules of Application shall apply to this Agreement. In case of conflict, the Financial Regulation and the Rules of Application shall prevail over this Agreement.
2. The following provisions apply to information handled under this Agreement:
  - (a) Article 339 of the Treaty on the obligation of professional secrecy;
  - (b) Article 57 of the Financial Regulation;
  - (c) Article 32 of the Rules of Application on the absence of conflicts of interest;
  - (d) the second subparagraph of Article 113(2) of the Financial Regulation on the non-disclosure of certain information emanating from the procurement procedure; and
  - (e) Article 155(3) of the Rules of Application on the secrecy of tenders.
3. Without prejudice to the first paragraph of Article 133 of the Rules of Application, each Member State shall remain responsible for compliance with any procedural requirements under its national law.

### Article 4

#### **Powers granted to the Commission on behalf of the Contracting Parties**

1. Where a binding act is adopted by the Commission further to and in accordance with this Agreement, that act shall bind all Contracting Parties, or, where applicable, only those Contracting Parties concerned by that act.
2. Subject to this Agreement, each Contracting Party authorises the Commission to act on its behalf in accordance with Union law in:
  - (a) the conduct of the joint procurement procedure(s) including the award of the framework or direct contract(s);
  - (b) the management of the framework contract(s) including the signature of any amendment of a non-substantial nature, in accordance with Article 122 of the Rules of Application.

Specific contracts following a joint procurement procedure conducted pursuant to this Agreement shall be concluded and managed on an individual basis by each Contracting Party, in accordance with Article 27.

3. The Contracting Parties authorise the Commission to act as their sole representative in instituting or defending any legal proceedings brought by a contractor under a framework contract, except for any legal proceedings brought against a Contracting Party under a specific contract based on a framework contract entered into pursuant to Article 122 of the Rules of Application.

The Commission, as sole representative of the Contracting Parties, shall seek the opinion of the relevant Specific Procurement Procedure Steering Committee (the "SPPSC") on the conduct of any legal proceedings covered by this paragraph at the first available opportunity, in accordance with Article 7 of this Agreement.

4. The Contracting Parties hereby authorise the Commission to act as their sole representative in bringing any legal proceedings against a contractor under a framework contract, except for any legal proceedings under a specific contract based on a framework contract entered into pursuant to Article 122 of the Rules of Application.

The Commission's authority under the first subparagraph is subject to the approval by the relevant SPPSC to institute such legal proceedings in accordance with Article 7, upon a proposal from a participating Contracting Party or from the Commission. Thereafter, the Commission shall seek the opinion of the relevant SPPSC on the conduct of any legal proceedings covered by this paragraph at the first available opportunity, in accordance with Article 7 of this Agreement.

5. The Commission may settle any disputes, legal proceedings brought under paragraphs 3 or 4 following the approval by the relevant SPPSC based on a proposal to this effect from a participating Contracting Party or from the Commission, in accordance with Article 7 of this Agreement.

## Title II

### **ORGANISATION**

#### Chapter I

#### **Steering Committees**

##### Article 5

#### **Duties**

1. A Joint Procurement Agreement Steering Committee (the "JPASC") is hereby established. The JPASC shall be responsible for steering matters relating to the subject matter of this Agreement, including:
  - (a) decisions, in particular, on the type of medical countermeasures to be procured under this Agreement and on the order in which such procurements will be organised in time;
  - (b) any legal proceedings under the joint procurement procedure which concerns all Contracting Parties;
  - (c) the process necessary to address any lack of compliance with this Agreement by a Contracting Party;
  - (d) the amicable settlement of disagreements between two or more Contracting Parties;
  - (e) amendments to this Agreement, in accordance with Article 46.

Where a binding act is adopted by the JPASC pursuant to this paragraph, that act shall bind all Contracting Parties.

2. Participating Contracting Parties shall set up a SPPSC which shall be responsible for steering matters relating to the subject matter of the specific procurement, including:
  - (a) the specific joint procurement procedure;
  - (b) any legal proceedings under the framework contract;
  - (c) the determination and application of allocation criteria, in accordance with Article 17(1);
  - (d) temporary deviations from the allocation criteria, in accordance with Article 17(2).

Where a binding act is adopted by a SPPSC pursuant to this paragraph, that act shall bind participating Contracting Parties.

3. The Steering Committees shall give opinions or approvals, in accordance with Article 7, as required by this Agreement.
4. Unless otherwise stated in this Agreement, the Steering Committees shall vote on proposals from the Commission.

## Article 6

## **Composition and Membership**

1. The Steering Committees shall be composed of one representative of each Contracting Party. A member may be replaced by an alternate.

Only staff of a Contracting Party may be members of the Steering Committees or their alternates.

2. The members of the Steering Committees and their alternates may, subject to their rules of procedure, be assisted by advisers.
3. The meetings of the Steering Committees shall be chaired by the Commission's representative or its alternate (the "Chair").

When it is not addressing the meeting as the Chair, the Commission's representative shall specify, that it is expressing the Commission's specific position as a Contracting Party.

4. The Commission shall ensure the secretariat of the Steering Committees.
5. The Contracting Parties shall, within fourteen days of signature of this Agreement, provide the Commission with information on the identity and contact details of their members of the JPASC, their alternates and any advisers assisting them.

The Contracting Parties wishing to participate in a joint procurement for a specific medical countermeasure shall, within fourteen days of a decision of the JPASC in this respect, provide the Commission with information on the identity and contact details of their members of the SPPSC, their alternates and any advisers assisting them.

The Commission shall draw up a list of the persons referred to in the second subparagraph based on the information provided by the Contracting Parties. The Contracting Parties shall notify one another of any changes in the identity and/or contact details of such persons.

6. The Steering Committees shall adopt their own rules of procedure, by a simple majority of their members, on a proposal from the Chair.
7. The Chair shall, within fourteen days of a meeting of the JPASC or of the SPPSC, provide the members of the relevant committee with a record of that meeting .

## Article 7

### **Procedure for opinions and approvals of the Steering Committees**

1. Where this Agreement requires the JPASC or the SPPSC to give an opinion or an approval on a proposal placed before it, the members of the relevant Steering Committee shall endeavour to act by common accord.

Abstentions by members of either the JPASC or the SPPSC shall not prevent the relevant Steering Committee from reaching a common accord.

Where the members of the JPASC or the SPPSC cannot achieve a common accord, they shall vote. The Chair shall determine when to call a vote.

2. An opinion of a Steering Committee shall be adopted by common accord or by a simple majority vote of its members.

An opinion delivered by a Steering Committee on a proposal laid before it in accordance with this Agreement shall not be binding on the Commission. However, in adopting a proposal, the Commission shall take into account, to the greatest extent possible, the opinion delivered.

A Steering Committee shall be considered to have approved a proposal if it is adopted by common accord or passed by a qualified majority of its members present or represented.

A qualified majority is defined as 55% of the present or represented members of the JPASC and representing Contracting Parties comprising at least 65% of the total amount of medical countermeasures covered by the joint procurement.

For proposals on matters that only concern the SPPSC, a qualified majority will be defined as 55% of its members 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 concerned Contracting Parties.

3. If a proposal is not passed by a qualified majority of the members of the relevant Steering Committee, present or represented, then, and without prejudice to paragraph 5, a second vote shall be organised at a subsequent meeting. By way of derogation from paragraph 3, the proposal shall be considered approved by a Steering Committee 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 where the actual cost is unknown, the estimated cost) of medical countermeasures covered by the joint procurement procedure, or, where applicable, covered by the Contracting Parties in the SPPSC.

If the proposal cannot be passed by such a simple majority, then, and without prejudice to paragraph 5, a third vote shall be held at a subsequent meeting. If the simple majority as defined in the first subparagraph again cannot be reached, the proposal shall be regarded as approved unless there is a qualified majority against it.

4. Where the approval of a proposal by a Steering Committee is required urgently, that Steering Committee shall meet via telephone or other appropriate means of distance

communication, and consecutive votes referred to in paragraph 3 can be held at the same meeting.

5. Notwithstanding the first subparagraph of paragraph 1, paragraphs 3 and 4 shall not apply where the unanimous agreement of the members of a Steering Committee is required under this Agreement.

## Chapter II

### **Evaluation Committees**

#### Article 8

##### **Duties**

1. Without prejudice to the third subparagraph of Article 158(1) of the Rules of Application, the Commission shall appoint an evaluation committee for the evaluation of requests to participate or tenders within the meaning of Article 111(5) of the Financial Regulation.
2. Notwithstanding paragraph 1, the Commission may appoint two separate evaluation committees:
  - (a) a committee for the selection of requests to participate or tenders on the basis of the exclusion and selection criteria; and
  - (b) a committee for the evaluation of tenders on the basis of the award criteria.

#### Article 9

##### **Composition and designation procedure**

1. The evaluation committee(s) shall be comprised of:
  - (a) no more than three persons designated by the Commission in accordance with the first subparagraph of Article 158(2) of the Rules of Application, including where the Commission is not concerned by the request to participate or tender;
  - (b) no more than five persons among those nominated by the participating Contracting Parties, other than the Commission, in accordance with the procedure laid down in paragraph 2. Such persons shall not be the same as those designated by the Commission.

The same person may be a member of both evaluation committees referred to in Article 8(2).

The evaluation committee shall be chaired by a Commission staff member that is a member of the relevant committee.

2. Upon the Commission's request, each participating Contracting Party shall nominate one candidate for membership of an evaluation committee by submitting to the Chair a completed pro-forma application form accompanied by information on the identity, education, professional qualifications and experience of the relevant nominee to the SPPSC through its Chair, in accordance with a pro-forma application. The pro-forma application form shall be adopted by the Commission, following approval by the SPPSC in accordance with the procedure laid down in Article 7.

A candidate shall only be nominated by one participating Contracting Party. Each nomination may be seconded by other participating Contracting Parties.

The Commission may refuse the appointment of a candidate nominated for membership of an evaluation committee where it has grounds to consider that the candidate has a conflict of interest within the meaning of Article 57 of the Financial Regulation. In such a case, the Contracting Party(ies) concerned shall nominate another candidate.

3. The Commission shall propose a list of members among those nominated by the participating Contracting Parties for approval by the SPPSC.

Where there are:

- a) no more than five participating Contracting Parties, other than the Commission, the Commission shall propose all the nominated candidates;
- b) six or more participating Contracting Parties, other than the Commission, the Commission shall propose a shortlist of five candidates.

The SPPSC shall assess the suitability of the candidates proposed. Within fourteen days of the date on which the Commission's proposal is sent out, any SPPSC member may require the Commission to:

- (a) interview any of the candidates nominated;
- (b) require additional information from the nominated candidates or the nominating Contracting Party(ies);
- (c) request the submission of the identity, education, professional qualifications and experience of further candidates, nominated pursuant to paragraph 2.

The Commission shall appoint the members of an evaluation committee referred to in paragraph 1(b) following approval by the SPPSC, in accordance with Article 7.



4. Members of an evaluation committee shall not participate in the work of the committee until they have signed the declaration of absence of conflict of interest and protection of confidentiality (the "Declaration") referred to in the first subparagraph of Article 37(5) with respect to the Contracting Party that has nominated or designated them or their employer.

Without prejudice to the third subparagraph of this paragraph, where a member of an evaluation committee is not employed by a Contracting Party, the Contracting Party shall enter into a contractual arrangement with the relevant employer by which the latter assumes full responsibility for any breach of the Declaration with respect to the Contracting Party concerned.

Each Contracting Party shall be responsible to every other Contracting Party for ensuring compliance with this paragraph and for making good any damage by a breach of the Declaration by a member of an evaluation committee nominated or designated by that Contracting Party.

5. The Commission shall draw up a list of the members of the evaluation committee. The Commission shall also keep duly certified copies of the signed Declaration.
6. Members of the evaluation committee(s) nominated by the participating Contracting Parties shall be appointed *ad personam*. When carrying out their tasks, they shall not seek or take instructions from Union institutions, bodies, offices or agencies, from any government of a Contracting Party or from any other body. The Contracting Parties undertake to respect this principle and not to seek to influence the members of the evaluation committee(s) in the performance of their tasks.

Members of the evaluation committee(s) shall not take part in any discussion, reaching of a common accord or vote taking place in a meeting of the SPPSC, which is based on any written record referred to in Article 10(3) to which they contributed.

7. Members of an evaluation committee shall resign if they are unable to honour the Declaration or are otherwise unable to carry out their functions, upon giving seven days' notice to the Chair of the SPPSC.
8. Any SPPSC member may request that a member of an evaluation committee may be removed for breach of the Declaration or if they are otherwise unable to carry out their function. A request to remove a member shall require the SPPSC's approval in accordance with Article 7.
9. Following the resignation or removal of an evaluation committee member nominated by a participating Contracting Party, the latter shall nominate a new member in accordance with the procedure laid down in paragraphs 2 and 3. Following the resignation or removal of an evaluation committee member from the Commission, the Commission shall designate a new member.

## Article 10

## **Procedure**

1. The Commission shall submit a proposal specifying the modalities for the application of Article 158(1) of the Rules of Application according to which the evaluation committee is to evaluate and rank the tenders on the basis of the award criteria only and where the exclusion and selection criteria are to be evaluated by other appropriate means guaranteeing the absence of conflicts of interests. The proposal shall be submitted to the SSPPCS for its approval in accordance with Article 7.
2. Tenders shall be evaluated in a non-discriminatory manner. Without prejudice to paragraph 1, the evaluation shall be based on the exclusion, selection and award criteria set out in the specifications referred to in Article 16(2)(b) or the requirements set out in any descriptive document for a competitive dialogue.
3. The evaluation committees shall keep a written record of their evaluation in accordance with Article 159(1) and (2) of the Rules of Application, which shall be drawn up by common accord.

Where the evaluation is conducted by means of two evaluation committees, as provided in Article 8(2), the written record of the evaluation based on the exclusion and selection criteria may be drawn up separately from the written record of the evaluation based on the award criteria.

## **Chapter III**

### **Common provisions**

#### **Article 11**

### **Organisation of meetings**

1. The Commission shall convene meetings of the JPASC, the SPPSC, the opening committee(s) and the evaluation committee(s).
2. To the extent practicable and subject to any urgency or unforeseen circumstances, meetings of the JPASC, the SPPSC, the opening committee(s) or evaluation committee(s) shall be convened at least fourteen days in advance of the scheduled date of the meeting.
3. To the extent practicable and subject to any urgency or unforeseen circumstances, and without prejudice to Article 37, information or documents relevant for the meetings referred to in paragraph 1 shall be submitted to the members of the JPASC, including any observers, the SPPSC, the opening committee(s) or evaluation committee(s), at least fourteen days in advance of the scheduled date of the meeting.

4. Meetings referred to in paragraph 1 shall be held either at a venue made available by the Commission or by audio or video-conference.
5. The Commission shall not reimburse travel, accommodation or any other *per diem* expenses of any person nominated by another Contracting Party taking part in the meetings referred to in paragraph 1.

### Title III

## PROCUREMENT PROCEDURE

### Article 12

#### **The Commission's role in the joint procurement procedure**

1. The Commission shall, as required under this Agreement, ensure the overall preparation and organisation of the joint procurement procedure and facilitate the amicable resolution of disagreements between Contracting Parties arising out of this Agreement and the operation of the joint procurement procedure.
2. The Commission shall act on its own account and on behalf of the Contracting Parties, as provided for in this Agreement.
3. The Commission shall be the sole representative of the Contracting Parties with regard to economic operators, candidates or tenderers throughout the joint procurement procedure, including any matters arising in relation to the joint procurement procedure following the award of framework contracts.
4. The Commission shall act as the sole representative of the Contracting Parties in any legal proceedings in accordance with Article 4, paragraphs 3 to 5, of this Agreement.
5. The Commission may request one or more Contracting Parties to assist it in its defence or pursuit of any legal proceedings. The requested Contracting Parties shall use their best endeavours to provide such assistance and shall refrain from taking any action that could jeopardise the defence or pursuit of any such legal proceedings.

A Contracting Party shall assist the Commission where that Contracting Party is named in an action.

6. The Commission shall provide administrative support in the course of the joint procurement procedure and the framework contracts. This includes:
  - (a) drawing up the necessary documentation and administrative correspondence on behalf of the Contracting Parties;

(b) keeping a record of the meetings of the JPASC, SPPSC, opening and evaluation committees;

(c) making appropriate arrangements for the handling of information or documents related to the joint procurement procedure or the framework contracts.

## Article 13

### **Start of a procurement procedure**

1. Any JPASC member may propose the launch of a procurement procedure. This proposal shall identify the medical countermeasures to be procured. A procurement procedure shall be started if at least five Contracting Parties, including the Commission, vote in favour of starting such procedure and have notified this intention to the Chair of the JPASC.
2. The Commission shall issue, after consulting the other Contracting Parties wishing to launch a procurement procedure, a reasonable deadline by which further Contracting Parties can express their interest in participating in the procurement procedure.
3. 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.

## Article 14

### **Type of procurement procedure**

1. Following the start of a procurement procedure in accordance with Article 13, the SPPSC shall decide, in accordance with Article 7, on the type of procurement procedure to be adopted, from amongst those listed in Article 104(1)(a) to (e) of the Financial Regulation on the basis of the principles laid down in Article 102 of that Regulation and Articles 127 and 137 of the Rules of Application.
2. The type of procurement procedure shall be specified in the contract notice referred to in Article 103 of the Financial Regulation and Article 123(3) of the Rules of Application.

## Article 15

### **Type and term of contract**

1. Following the start of a procurement procedure in accordance with Article 13, the SPPSC shall approve in accordance with Article 7, on:

- (a) the type of contract that will be awarded on the basis of the principles laid down in Article 101 of the Financial Regulation and Articles 121 and 122 of the Rules of Application;
  - (b) the duration of the framework contract as well as on the arrangements for its review in accordance with the first subparagraph of Article 122(1) and Article 122(4) of the Rules of Application.
2. The type of contract and its the duration shall be specified in the contract notice.

## Article 16

### **Content of Tender documents**

1. The content of all tender documents relating to a procurement procedure initiated in accordance with Article 13, shall be determined by the Commission in accordance with the relevant provisions of the Financial Regulation and the Rules of Application, subject to an opinion of the SPPSC, in accordance with Article 7.
2. Notwithstanding the first paragraph:
  - (a) the contract notice, including the description of lots if any;
  - (b) the technical specifications, and the exclusion, selection and award criteria;
  - (c) any descriptive document, in the case of a competitive dialogue procedure;
  - (d) the draft contract(s);
  - (e) the letter of invitation to tender setting up submission requirements;shall be adopted following approval by the SPPSC, in accordance with Article 7.

## Article 17

### **Allocation criteria**

1. The frequency with which available amounts of medical countermeasures are allocated between participating Contracting Parties ("the generally applicable allocation criteria") shall be submitted to the SPPSC for approval, in accordance with Article 7.

The Contracting Parties shall receive the total quantity of the medical countermeasures that they have reserved or ordered, but the rate of delivery shall depend on the production capacity of the contractor and on the generally applicable allocation criteria.

2. A Contracting Party may, on well-founded and substantiated grounds, such as problems encountered in delivery or due to urgent needs, request derogation from the generally applicable allocation criteria laid down in paragraph 1, for a specified time period.

Derogation shall only be permitted following approval by the SPPSC by common accord. The Chair shall inform the SPPSC of any approved derogations from the generally applicable allocation criteria, including the time periods for which such derogations are approved.

3. Paragraph 2 shall not prevent two or more Contracting Parties agreeing, on a bilateral basis, on a temporary derogation from the generally applicable allocation criteria agreed pursuant to paragraph 1 for a framework contract they have entered into, for the amounts to which they are entitled under those criteria.

Those Contracting Parties shall inform the SPPSC of any such agreement, including the duration of the temporary derogation agreed.

The terms of a temporary derogation from the generally applicable allocation criteria shall be agreed between the contractor and the agreeing Contracting Parties.

Where the medical countermeasures concerned are medicinal products, contractors shall ensure that the medicinal products are authorised to be placed on the market in the Member States of the Contracting Parties, in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001<sup>6</sup> or Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004<sup>7</sup>.

## Article 18

### **Publication of a contract notice**

1. After the tender documents have been prepared in accordance with Article 16 and approved by the SPPSC, the Commission shall publish a contract notice in the *Official Journal of the European Union*.
2. The Commission will make the tender documents referred to in paragraph 1 available to economic operators on request.

## Article 19

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<sup>6</sup> 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 (OJ L 311, 28.11.2001, p. 67).

<sup>7</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

### **Specific provisions regarding the opening of requests to participate or tenders**

1. Requests to participate and tenders shall be opened by an opening committee composed of persons representing the Commission in accordance with Article 111(4) of the Financial Regulation and Article 157 of the Rules of Application.
2. Any Contracting Party may request the Commission to allow one of its representatives to observe the opening of requests to participate or tenders.
3. Observers shall neither participate in the deliberations of the opening committee nor make known any views to members of that committee.
4. The Commission shall make available to the SPPSC members the written record of the opening of requests to participate or tenders referred to in the fourth subparagraph of Article 157(3) of the Rules of Application.

### Article 20

#### **Elimination of candidates or tenderers**

1. Without prejudice to the second subparagraph of Article 158(3) of the Rules of Application, only requests to participate or tenders that satisfy the requirements in accordance with the first subparagraph of Article 158(1) of the Rules of Application, and that are not excluded on the basis of the exclusion criteria and which meet the selection criteria, shall be considered admissible for evaluation under the award criteria, as provided for in the third subparagraph of Article 158(3) of the Rules of Application .
2. For the purpose of the first paragraph, and in accordance with Article 10(2), the evaluation committee shall examine whether the exclusion criteria and the selection criteria are met by each request to participate or tender. Where, due to an obvious clerical error on the part of the candidate or tenderer, the candidate or tenderer omits to submit evidence or to make statements, Article 96(2) of the Financial Regulation shall apply.

Where the evaluation committee concludes that a candidate or tenderer meets the exclusion criteria and/or does not meet the selection criteria, the Commission shall submit a proposal excluding or declaring unsuccessful that candidate or tenderer for the approval of the SPPSC, in accordance with Article 7. Such a decision shall prevent that candidate or tenderer from participating in any further stage of the joint procurement procedure.

The Commission's proposal shall be accompanied by the written records of the evaluation referred to in Article 10(3) and shall indicate the reasons for excluding or declaring unsuccessful the candidate or tenderer concerned.

- 3 The Commission shall notify each candidate or tenderer that has been excluded or declared unsuccessful pursuant to this Article of the reasons for its decision.

The notification shall be made in accordance with point (a) of the first subparagraph of Article 161(3) and the second subparagraph of Article 161(3) of the Rules of Application. Such notification shall be made as soon as practicable following the opinion of the SPPSC.

## Article 21

### **Award of a contract**

1. The award decision shall be adopted by the Commission on its own behalf and on behalf of the participating Contracting Parties, in accordance with Article 113(1) of the Financial Regulation and Articles 149 and 159(3) of the Rules of Application, after approval by the Specific Procurement Procedure Steering Committee in accordance with Article 7.
2. The Commission proposal shall be accompanied by a copy of the written records of the evaluation referred to in Article 10(3), as well as, where the Commission proposes not to follow the recommendations of the evaluation committee, by a note substantiating the reasons for which they are not being followed.
3. The award decision shall be notified simultaneously to all successful and unsuccessful tenderers or candidates in accordance with Article 161(3) of the Rules of Application.

## Article 22

### **Specific provisions relating to the signature of the contract and entry into force**

1. After the award decision is adopted, and without prejudice to Article 114 of the Financial Regulation, the participating Contracting Parties shall sign the contract.
2. A contract with a selected tenderer shall be approved by the SPPSC in accordance with Article 7, before it is signed if or to the extent that it differs substantively from the draft contract, approved in accordance with Article 16(2)(d).

For the purposes of the first subparagraph, a contract with a selected tenderer shall not be deemed to differ substantively from a draft contract where differences are limited to the insertion of particulars that are missing in the draft contract.

3. The signing of the contract shall be subject to the rules on standstill provided for in Article 171 of the Rules of Application.
4. The contract shall not enter into force until it is signed by the contractor and the participating Contracting Parties pursuant to paragraph 1.



5. In cases of urgency, after the award decision is adopted and without prejudice to Article 114 of the Financial Regulation, the SPPSC may approve, in accordance with Article 7, to authorise the Commission to sign the framework contract on behalf of and for the account of all the participating Contracting Parties.

## Article 23

### **Specific provisions relating to contacts with economic operators, candidates or tenderers during the joint procurement procedure**

1. The Commission shall be the sole point of contact between the Contracting Parties and economic operators, candidates, tenderers, or their representatives, concerning any matter pertaining to the joint procurement procedure.

The Commission shall adopt and publish arrangements for contact with economic operators or their representatives on its website prior to the launch of the joint procurement procedure.

After the launch of a joint procurement procedure, contact between economic operators, candidates, tenderers, or their representatives and the Commission as well as other Contracting Parties or their representatives may only take place, by way of exception, under the conditions set out in Article 160(2) and (3) of the Rules of Application.

2. Each Contracting Party shall ensure that, where persons working in connection with this Agreement for that Contracting Party are approached by an economic operator, candidate, tenderer, or their representative concerning any matter pertaining to the joint procurement procedure following the entry into force of this Agreement, they shall state that, under Article 23(1) of this Agreement, the Commission is the sole contact point with economic operators, candidates, tenderers, or their representatives and refer any such person to the Commission. They shall simultaneously inform the Commission of the details of the approach and the referral.
3. Any contact with economic operators, candidates, tenderers or their representatives referred to in paragraphs 1 and 2, including any exchange of correspondence involved, shall be duly recorded.

The Commission shall inform the SPPSC of such contacts.

4. The Contracting Parties retain the right to communicate with the economic operators, candidates, tenderers or their representatives in relation to procurement procedures outside this Agreement, including in relation to procedures which involve the procurement of medical countermeasures which form the subject of a joint procurement procedure, but shall not, in doing so, refer to any matter pertaining to that particular joint procurement procedure.

## Article 24

## **Abandonment and cancellation**

1. Contracting Parties that have started a procurement procedure may, for well-founded and substantiated grounds, collectively abandon the joint procurement procedure before the contract is awarded or collectively cancel the award procedure before the contract is signed, pursuant to the first paragraph of Article 114 of the Financial Regulation.

Such a decision shall be adopted by the Commission after approval by the SPPSC, upon a proposal from the Commission or any other participating Contracting Party. By way of derogation from Article 7, the proposal shall stand adopted if a simple majority of the SPPSC members present or represented vote in favour of the collective abandonment or collective cancellation.

2. For the application of Article 114 of the Financial Regulation, the call for tender shall provide that the participating Contracting Parties may either abandon the joint procurement procedure before the contract is awarded or cancel the award procedure before the contract is signed, without the candidates or tenderers being entitled to claim any compensation.
3. Even if a proposal has been approved in accordance with paragraph 1, the SPPSC may only abandon the joint procurement procedure before the contract is awarded or cancel the award procedure before the contract is signed.

The decision of the SPPSC under the first subparagraph shall be brought to the attention of the candidates or tenderers as soon as practicable.

4. A Contracting Party that has started a joint procurement procedure may, for well-founded and substantiated grounds, individually abandon that procedure before the contract is awarded, pursuant to the first paragraph of Article 114 of the Financial Regulation.

A Contracting Party shall give reasons for its decision which shall be communicated to the SPPSC, the candidates or tenderers.

5. For the application of Article 114 of the Financial Regulation, the call for tender shall provide that a Contracting Party may abandon the joint procurement procedure before the contract is awarded, without the candidates or tenderers being entitled to claim any compensation.

## Article 25

### **Specific provisions applicable in the case of a negotiated procedure**

1. Where the joint procurement is pursued through a negotiated procedure, paragraphs 2 to 8 shall apply to:

- (a) the invitation to submit offers for negotiation;
  - (b) the negotiations with tenderers or their representatives;
  - (c) the evaluation of the tenders.
2. In negotiated procedures without prior publication of a contract notice in the *Official Journal of the European Union*, the Commission shall submit a draft shortlist of candidates that it proposes to invite to negotiate, for approval by the SPPSC, in accordance with Article 7.
  3. Following the approval referred to in paragraph 2, the Commission shall, on behalf of the participating Contracting Parties, invite the shortlisted candidates to negotiate.
  4. In negotiated procedures, following publication of a contract notice in the *Official Journal of the European Union*, the procedure may take place in stages by applying the award criteria set out in the tender specifications to reduce the number of tenders to be negotiated. If so, the tender specifications shall stipulate that this option is to be used and shall indicate how it shall be used.

If the option envisaged under the first subparagraph is used, an evaluation committee set up in accordance with Articles 8 and 9 shall submit an evaluation report, for approval by the SPPSC in accordance with Article 7, with a list of tenderers to be eliminated from participating in further stages of the joint procurement procedure based on application of the award criteria.

5. Following approval as referred to in [the second subparagraph of] paragraph 4, the Commission, acting on behalf of the participating Contracting Parties, shall notify each excluded tenderer of the reasons for its exclusion from further stages of the joint procurement procedure.

The notification shall be made in accordance with Article 161(3) of the Rules of Application. Such notification shall be made as soon as practicable following the approval by the SPPSC.

6. The negotiations shall be conducted by (an) evaluation committee(s) set up in accordance with Articles 8 and 9 with tenderers that have not been excluded or declared unsuccessful in accordance with Article 20(2) or through the application of the option envisaged under paragraph 4 of this Article.
7. The negotiations shall be carried out in accordance with Article 129 of the Rules of Application and on the basis of pre-announced criteria provided for in the tender specifications.

Where the negotiations are conducted orally, a written record of the negotiations shall be drawn up by the evaluation committee(s) referred to in paragraph 6. It shall be sent to the tenderer concerned, indicating a time limit for communicating any proposed addition or correction. During meetings with tenderers, the evaluation committee(s) shall be represented by at least two members, one of whom is designated by the

Commission and another nominated by a Member State. Oral negotiations may only be conducted where there is only one candidate, due to a monopoly situation, pursuant to Article 134(1)(b) or if the negotiations take place with a tenderer awarded the initial contract, in situations referred to in Article 134(1)(e) or (f) of the Rules of Application.

Unless otherwise specified in the tender documents, the negotiations shall be strictly limited to the content of the tender and shall not modify initial terms of the technical specifications and/or contractual provisions.

8. During the negotiations, tenderers may be requested by the evaluation committee(s) to modify their tenders, in which case their offers shall be evaluated on the basis of their modified tenders.

## Article 26

### **Specific provisions applicable in the case of a competitive dialogue**

1. Where the joint procurement is pursued through a competitive dialogue procedure, paragraphs 2 to 7 shall apply to dialogues with candidates and their representatives that have not been excluded or declared unsuccessful in accordance with Article 20(2) or through the application of the option envisaged in paragraph 3 of this Article.
2. The dialogues shall be conducted by (an) evaluation committee(s) set up in accordance with Articles 8 and 9, in conformity with Article 132 of the Rules of Application.

A written record of the dialogues shall be drawn up by the evaluation committee(s) referred to in the first subparagraph. It shall be sent to the candidate concerned, indicating a time limit for communicating any proposed addition or correction. The evaluation committee(s) shall also draw up a report setting out its overall assessment of and recommendations on the results of the dialogues, in particular on whether or not the dialogues should be concluded.

The dialogues shall not concern the contract notice or descriptive document referred to in Article 132 of the Rules of Application.

3. The dialogues may take place in successive stages in order to reduce the number of solutions to be discussed by applying criteria set out in the descriptive document accompanying the contract notice. Where that is the case, the descriptive document shall stipulate that this option is to be used and indicate how it shall be used.

If the option envisaged under the first subparagraph is used, an evaluation committee set up in accordance with Articles 8 and 9 shall submit an evaluation report, for approval by the SPPSC in accordance with Article 7, with a list of candidates to be excluded from participating in further stages of the joint procurement procedure based on application of the criteria set out in the descriptive document.

4. Following approval as referred to in [the second subparagraph of] paragraph 3, the Commission acting on behalf of the participating Contracting Parties shall notify each candidate that has been so excluded of the reasons for their exclusion from further stages of the joint procurement procedure.

The notification shall be made in accordance with Article 161(3) of the Rules of Application. Such notification shall be made as soon as practicable following the approval by the SPPSC.

5. Before concluding the dialogues, a proposal informing candidates that the dialogues are concluded and inviting them to submit their final tenders on the basis of solutions presented and specified during the dialogues, shall be submitted by the Commission for the approval by the SPPSC in accordance with Article 7.
6. Following approval as referred to in paragraph 5, the Commission, acting on behalf of the concerned Contracting Parties, shall notify each participant in the dialogues that has not been eliminated under paragraph 4 of the conclusion of the dialogues and shall invite them to submit their final tenders on the basis of solutions presented and specified during the dialogue.

The notification shall be made in accordance with Article 113(2) of the Financial Regulation and Article 161(3) of the Rules of Application. Such notification shall be made as soon as practicable following the approval by the SPPSC.

7. The tenders submitted shall be evaluated by the evaluation committee(s) referred to in paragraph 2, in conformity with the second and third subparagraphs of Article 132(4) of the Rules of Application.

#### Title IV

### **AWARD AND USE OF SPECIFIC CONTRACTS BASED ON FRAMEWORK CONTRACTS**

#### Article 27

##### **Award and signature of specific contracts based on framework contracts**

1. The implementation of framework contracts shall be carried out through specific contracts concluded between individual participating Contracting Parties and the JPA contractors that are parties to these framework contracts.

Contracting Parties concerned by a framework contract may award and sign specific contracts up to the maximum number of medical countermeasures they have reserved under the said framework contract.

2. Any Contracting Party shall inform the JPASC of the award and conclusion of specific contracts in a timely manner.

3. Specific contracts shall be signed by all parties to the framework contract before that framework contract expires. Those specific contracts shall be implemented at the latest 6 months after the expiry of the relevant framework contract. The provisions of the relevant framework contract shall continue to apply to such specific contracts after its expiry.
4. Contracting Parties awarding and signing specific contracts shall be fully responsible for the implementation of these contracts and, in particular, the following tasks:
  - a) ensuring compliance with the terms of the framework contract when implementing it through a specific contract;
  - b) informing the Commission of the quality and of the quantity of the supplies that would be delivered;
  - c) where applicable, evaluating the offers for specific contracts in case of reopening of competition;
  - d) making individual budgetary commitments;
  - e) issuing order forms;
  - f) ensuring the follow-up of order forms;
  - g) meeting payment deadlines obligations;
  - h) managing the contractual relations stemming from specific contracts;
  - i) respecting the obligation of ex-post publication of the award of the contract.

#### Article 28

##### **Reallocation of reserved quantities**

A Contracting Party may offer its reserved quantity of medical countermeasures under a framework contract wholly or in part to one or more Contracting Party participating in the same framework contract. The terms of reallocation of reserved quantities shall be agreed between the offering Contracting Party and the acquiring Contracting Party.

#### Article 29

##### **Redirection of orders**

1. Following the award of a specific contract under a framework contract, a Contracting Party may offer to one or more Contracting Party participating in the same framework contract to purchase wholly or in part the ordered quantity still remaining with the contractor. The terms of redirecting the ordered quantities shall be agreed between the contractor, the offering Contracting Party and the acquiring Contracting Party.
2. Where the medical countermeasures concerned are medicinal products, the acquiring Contracting Party shall ensure that those medicinal products comply with Directive 2001/83/EC<sup>6</sup> or Regulation (EC) No 726/2004<sup>7</sup>.

## Article 30

### **Resale of deliveries**

1. A Contracting Party may offer to one or more other Contracting Party the possibility of purchasing a number of medical countermeasures that have already been delivered to the offering Contracting Party. The terms of the resale shall be agreed between the offering Contracting Party and the acquiring Contracting Party, and, if applicable, the contractor.
2. The offering Contracting Party and the acquiring Contracting Party shall ensure that such resale is in compliance with public procurement law and competition law and respects any contractual stipulations by which the offering Contracting Party may be bound.
3. Where the medical countermeasures concerned are medicinal products, the acquiring Contracting Party shall ensure that those medicinal products comply with Directive 2001/83/EC<sup>6</sup> or Regulation (EC) No 726/2004<sup>7</sup>.
4. The possibility to resell medical countermeasures that have already been delivered to a Contracting Party to one or more state that is not a Contracting Party is subject to the agreement of the offering Contracting Party, the acquiring state(s), and the contractor. The offering Contracting Party and the acquiring state(s) shall ensure that such resale is in compliance with Union public procurement law and competition law and respects any contractual stipulations by which the offering Contracting Party may be bound.

## Article 31

### **Donation of medical countermeasures**

1. A Contracting Party may donate medical countermeasures acquired under the joint procurement procedure.
2. Before the donation, the Contracting Party shall inform the JPASC. JPASC members shall have seven calendar days to express their interest to receive the donation. After this period, the donating Contracting Party may decide on the beneficiary of the donation, taking into account the public health needs of the states represented by the

JPASC member(s), and of other states and international organisations, that have expressed their interest.

3. The donating Contracting Party may claim the reimbursement of administrative expenditures and transport costs from the receiving country that it bears in relation to the donation.

## Title V

### **PROVISIONS APPLICABLE TO THE HANDLING OF INFORMATION OR DOCUMENTS**

#### Article 32

##### **Sharing of information or documents**

The Contracting Parties shall provide each other with the information or documents required for the purposes of carrying out their respective roles under this Agreement.

#### Article 33

##### **Professional secrecy**

1. Without prejudice to paragraph 2, persons working in connection with this Agreement shall be prohibited, even after their duties have ceased, from disclosing information of the kind covered by the obligation of professional secrecy within the meaning of Article 339 of the Treaty.
2. Without prejudice to Article 35(2), information or documents covered by the obligation of professional secrecy handled by the Contracting Parties under this Agreement shall be disseminated only according to the needs of persons working in connection with this Agreement to enable them to perform a function or a task in connection with this Agreement. Access shall not be authorised merely because a person occupies a particular position, however senior.

Once the information or documents referred to in the first subparagraph have lawfully been made publically available, the obligation of professional secrecy shall no longer apply.

3. Each Contracting Party shall be responsible for ensuring that all persons working for it in connection with this Agreement are legally bound to respect the obligations in paragraphs 1 and 2 during their employment and following the termination of their employment.
4. Without prejudice to Article 38(1), where persons working in connection with this Agreement are not employed by a Contracting Party, the Contracting Party that they



are assisting shall enter into a contractual arrangement with the relevant employer by which the latter imposes the obligations in paragraphs 1 and 2 on its employees.

#### Article 34

##### **Conflict of interest**

1. Each Contracting Party shall be responsible for ensuring that all persons working for it in connection with this Agreement are not in a situation that might create a conflict of interest or otherwise compromise the impartiality or objectivity of their work in connection with this Agreement during their employment.
2. Without prejudice to Article 38(1), where persons working in connection with this Agreement are not employed by a Contracting Party, the Contracting Party that they are assisting shall enter into a contractual arrangement with the relevant employer by which the latter imposes the obligations in paragraph 1 on its employees.

#### Article 35

##### **Use of Information or Documents**

1. The Contracting Parties shall not use any information or document handled under this Agreement for purposes other than those pertaining to this Agreement.
2. To the extent possible under the applicable Union or national law, any Contracting Party considering the release of any information or document handled under this Agreement, shall consult in writing the originator of the information or document in good time prior to releasing the information or document in question, and shall take the utmost account of the views of the originator.

Where prior consultation in accordance with the first subparagraph is not possible, the Contracting Party shall nonetheless inform the originator of the release including the factual and legal circumstances pertaining to it without undue delay.

3. Each Contracting Party shall be responsible for ensuring that all persons working for it in connection with this Agreement are legally bound to respect the obligations in paragraphs 1 and 2 during their employment and following the termination of their employment.
4. Without prejudice to Article 37(1), where persons working in connection with this Agreement are not employed by a Contracting Party, the Contracting Party that they are assisting shall enter into a contractual arrangement with the relevant employer by which the latter imposes the obligations in paragraphs 1 and 2 on its employees.

#### Article 36

## **Access to documents**

Nothing in this Agreement shall preclude a Contracting Party from complying with provisions of Union or national law applicable to it regarding public access to documents, the protection of personal data or the protection of classified information.

### Article 37

#### **Measures for protecting information or documents handled under this Agreement**

1. The Commission shall propose specific handling instructions applicable to information or documents handled under this Agreement and security measures applicable to meetings of the JPASC, the SPPSC and the opening or evaluation committees.
2. Handling instructions applicable to information or documents handled within the JPASC and security measures applicable to meetings of the JPASC shall be adopted as part of the rules of procedure of this committee on the basis of a proposal from the Commission.
3. Handling instructions applicable to information or documents handled within the SPPSC and security measures applicable to meetings of the SPPSC shall be adopted as part of the rules of procedure of this committee on the basis of a proposal from the Commission.
4. Handling instructions applicable to information or documents handled within the opening or evaluation committees and security measures applicable to meetings of the opening or evaluation committees, including any Code of conduct for evaluators, shall be submitted to the JPASC for approval pursuant to Article 7.
5. Each member of the evaluation committees shall sign the Declaration.

The Chair of an evaluation committee may also require each member of the evaluation committee to sign a Code of conduct for evaluators referred to in the paragraph 4.

### Article 38

#### **Compliance**

1. Each Contracting Party shall be responsible to every other Contracting Parties for ensuring compliance with this Title and for making good any damage caused by the breach of those provisions.
2. Each Contracting Party shall take appropriate measures in accordance with the rules, laws or regulations applicable to it, to:

- (a) prevent and detect the disclosure of information or documents covered by the obligation of professional secrecy handled under this Agreement to unauthorised persons;
  - (b) comply with handling instructions relating to information or documents covered by the obligation of professional secrecy handled under this Agreement;
  - (c) prevent, detect and eliminate conflicts of interests that may arise in the performance of this Agreement.
3. Each Contracting Party shall notify the JPASC, through its Chair, of any breach of this Title or where information or documents protected under this Title have been lost or inappropriately handled, without undue delay, upon becoming aware of such a breach, loss or inappropriate handling.

The Contracting Party concerned shall promptly investigate, in accordance with the rules, laws or regulations applicable to it, the breach, loss or inappropriate handling of the information or documents, where it is known or where there are reasonable grounds for suspecting that the information or documents covered by the obligation of professional secrecy handled under this Agreement may have been lost or inappropriately handled. It shall report to the JPASC on the results of its investigation.

Without prejudice to the rules, laws or regulations applicable to them, the Contracting Parties shall co-operate with one another in the investigation of any breach of this Title or where information or documents protected under this Title have been lost or inappropriately handled.

Without prejudice to the fifth subparagraph, the Contracting Parties shall co-operate with one another in finding appropriate solutions to eliminate, remedy or mitigate the impact of any breach of this Title.

Each Contracting Party shall remain responsible for eliminating, remedying or mitigating the impact of any breach of this Title, even after having consulted the JPASC.

## Title VI **FINAL PROVISIONS**

### Article 39

#### **Duty of sincere co-operation**

The Contracting Parties shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Agreement or from any action

taken under it. They shall abstain from any measure that could jeopardise the attainment of the objectives of Decision No 1082/2013/EU and this Agreement.

This Article is without prejudice to the right of Contracting Parties to carry out procurement procedures outside this Agreement, even where such procedures involve the procurement of medical countermeasures which form the subject of a joint procurement procedure or a framework contract or involve economic operators or contractors who are tendering for, or have signed, a framework contract pursuant to a joint procurement procedure under this Agreement.

## Article 40

### **Consequences of non-compliance**

1. In the event of a failure to comply by any Contracting Party with this Agreement, the Contracting Parties shall use their best endeavours to promptly and jointly determine together in the JPASC the means to redress the situation as soon as possible.
2. In the event of a disagreement between two or more Contracting Parties with regard to the interpretation or application of this Agreement, those Contracting Parties shall use their best endeavours to settle the matter directly.

Should this not be possible, any of the Contracting Parties to the disagreement may refer the matter to the JPASC, where the Contracting Parties shall use their best endeavours to resolve the matter through mediation.

3. If the processes set out in paragraphs 1 and 2 do not remedy the lack of compliance or settle the disagreement, within three months of the matter being referred to the JPASC either under paragraph 1 or the second subparagraph of paragraph 2, the matter may be referred to the Court of Justice in accordance with Article 41.

## Article 41

### **Competent court for hearing disagreements**

1. Any failure to comply with this Agreement, or disagreement with regard to the interpretation or application of this Agreement between the Contracting Parties, that remains unresolved within the JPASC, following the application of Article 40(3), may be brought before the Court of Justice:
  - (a) by the Contracting Party(ies) concerned, pursuant to Article 272 of the Treaty, where the unresolved matter is outstanding between the Commission and one or more Member State;
  - (b) by any Contracting Party(ies) concerned that is(are) (a) Member State(s) of the Union, against any other Contracting Party(ies) concerned that is(are) (a)

Member State(s) of the Union, pursuant to Article 273 of the Treaty , where the unresolved matter is outstanding between two or more Member States.

2. The Court of Justice shall have exclusive jurisdiction to decide upon any failure to comply with this Agreement or disagreement with regard to the interpretation or application of this Agreement.
3. The Court of Justice may award any remedy it deems appropriate in cases brought before it under this Article.

#### Article 42

##### **Applicable law and severance**

1. Matters or disputes arising within the subject matter of this Agreement shall be governed by applicable Union law, the terms of this Agreement and, where appropriate, the general principles of law common to the Member States of the Union.
2. The law applicable to framework or direct contracts pursuant to this Agreement and the competent court for the hearing of disputes under these contracts shall be determined in these contracts.
3. If any one or more of the provisions of this Agreement should be or become fully or partly invalid, illegal or unenforceable in any respect under the applicable law, the validity, legality and enforceability of the remaining provisions contained therein shall not be affected or impaired thereby.

#### Article 43

##### **Non-contractual liability and indemnity for actions for damages**

1. Without prejudice to Articles 41 and 42, each Contracting Party shall, in accordance with Union law, make good any non-contractual damage to third parties or to other Contracting Parties, arising out of this Agreement caused by its authorities or by any persons working in connection with this Agreement for those authorities.

The Commission's non-contractual liability arising out of this Agreement is governed by the second paragraph of Article 340 of the Treaty.

2. Without prejudice to Articles 41 and 42, where the Commission, within its role as a representative of the Contracting Parties pursuant to Article 4, paragraphs 3 to 5, is required to compensate a third party or a Contracting Party for non-contractual damage arising in connection with this Agreement caused in whole or in part by one or more Contracting Party(ies) and where the Contracting Party(ies) concerned can be identified, the Contracting Party(ies) in question shall indemnify the Commission in full for the cost of making good any damage not caused by the Commission, including the related costs of any legal proceedings.

3. Without prejudice to Articles 41 and 42, where the Commission, within its role as a representative of the Contracting Parties pursuant to Article 4, paragraphs 3 to 5, is required to compensate a third party or another Contracting Party for non-contractual damage arising in connection with this Agreement caused in whole or in part by one or more Contracting Party(ies) but where the Contracting Party(ies) concerned cannot be identified, all the other Contracting Parties shall indemnify the Commission for the cost of making good this damage, including the related costs of any legal proceedings.

The share payable by each Contracting Party concerned, including the share that remain borne by the Commission, of the total cost of this compensation shall be in accordance with its share in the total number of medical countermeasures covered by the specific procurement procedure.

A Contracting Party shall be excluded from the calculation if it can prove that it could not have caused the damage even in part. However, no Contracting Party shall be excluded from the calculation solely on the grounds that it was not part of the JPASC or the SPPSC that approved or gave an opinion in favour of a proposal which once adopted caused the damage, either because it was not present or represented at the meeting, or because it did not take part in the vote; nor shall a Contracting Party be excluded from the calculation on the grounds that it abstained from voting, or voted against the proposal.

4. Without prejudice to Articles 41 and 42, where the Commission has suffered non-contractual damage arising out of this Agreement caused in whole or in part by one or more Contracting Parties but where the Contracting Party concerned cannot be identified, all the Contracting Parties other than the Commission shall indemnify the Commission in full for the cost of this damage.

The share payable by each Contracting Party concerned of the total amount due to the Commission shall be calculated in accordance with the second subparagraph of paragraph 3. The third subparagraph of paragraph 3 shall apply accordingly.

- 5 Without prejudice to Articles 41 and 42, the Commission, as opposed to the other Contracting Parties, shall be solely responsible to make good any non-contractual damage, arising out of this Agreement, caused to a third party or (an) other Contracting Party(ies) by acts the Commission has adopted without the approval or opinion of the Steering Committees under this Agreement.
- 6 This Article shall not apply to contractual liability arising under the contracts.

#### Article 44

#### **Terms of Payment and Prices**

1. Participating Contracting Parties shall comply with all prices and terms of payment specified in the:

- (a) descriptive document accompanying the contract notice, in the case of a competitive dialogue procedure, in favour of participants in the dialogue;
  - (b) framework contract with the contractor following its conclusion.
2. Participating Contracting Parties shall be responsible for settling directly with the contractor any financial commitments resulting from a framework contract, *pro rata* to their share in the total number of medical countermeasures covered by that framework contract.

#### Article 45

### **Preamble and Annexes**

This Agreement shall be interpreted in the light of its Preamble and Union Law, in particular, Decision No 1082/2013/EU, the Financial Regulation and the Rules of Application. The Annexes to this Agreement shall constitute an integral part thereof.

#### Article 46

### **Amendments**

The Contracting Parties may propose amendments to this Agreement. The proposed amendments shall be submitted in writing to the JPASC, through its Chair.

An amendment to this Agreement and its Annexes shall be unanimously agreed by the JPASC. The amendment enters into force and becomes an integral part of this Agreement in accordance with the fourth and fifth paragraphs of Article 51.

#### Article 47

### **Term and termination**

1. This Agreement shall subsist until it is either replaced by another agreement in accordance with paragraph 2 of this Article or it is terminated in accordance with paragraph 3 of this Article.
2. Upon a request presented by a simple majority of the JPASC members, the Commission may develop a proposal either to replace this Agreement with another agreement or to terminate this Agreement. The Commission proposal shall, if appropriate, be accompanied by a comprehensive plan for an orderly transition to an alternative framework and the continuation of the guarantees in the interim.
3. This Agreement shall only be terminated if agreed in writing unanimously by the Contracting Parties.

## Article 48

### **Withdrawal by a Contracting Party**

1. Should a Contracting Party decide to withdraw from the Agreement, the Contracting Party shall inform the JPASC. Withdrawal from the Agreement shall not have financial consequences for withdrawing Contracting Parties provided that the withdrawal takes effect before the call for tender is published.
2. The withdrawing Contracting Party shall compensate any damages resulting from its contractual obligations under contracts governed by this Agreement.

## Article 49

### **Other countries joining this Agreement**

1. This Agreement shall be open to the participation of any Member State of the Union, as well as, subject to the conclusion of international agreements to that effect as required under Article 104(1), fourth subparagraph, of the Financial Regulation, of any EFTA state or Union candidate country.
2. Should a country among those referred to in paragraph 1 decide to join the Agreement, it shall inform the Contracting Parties in writing, through the JPASC.
3. The signature of the Agreement by a joining country means that it accepts unconditionally all stipulations of this Agreement as well as all decisions already adopted by the Commission and the JPASC in connection with this Agreement as of when the Agreement entered into force as set out in Article 51(4). The joining country cannot, however, participate in on-going procurement procedures.

## Article 50

### **Communication**

All notices under this Agreement shall be valid if given in writing and sent to the addresses and contact details by the transmission means provided for in the rules of procedure of the JPASC.

## Article 51

### **Signature and entry into force**



1. This Agreement shall be established and executed in the equally authentic linguistic versions set out in Annex IV.
2. The Contracting Parties shall sign one or more duplicates of each of the linguistic versions of this Agreement. Signatures on different duplicates of an authentic linguistic version shall have the same effect as if the signatures were on a single duplicate of this Agreement.
3. The Commission shall act as depository of all signed authentic linguistic versions of this Agreement. It shall supply duly certified copies of this Agreement to each of the Contracting Parties as soon as practicable after the receipt of signed duplicates of this Agreement from all Contracting Parties.
4. This Agreement shall enter into force 14 days following the day on which the Commission has received a signed duplicate of this Agreement from each Contracting Party in all authentic linguistic versions, the Commission has signed a duplicate in the same authentic linguistic versions, and one third of all Contracting Parties have submitted to the Commission the Confirmation of completion of national procedures for the approval of this Agreement or the absence of a need for such procedures, attached as Annex II.
5. The remaining two thirds of Contracting Parties to submit the Confirmation referred to in paragraph 4 shall be bound, as of 14 days following submission of that Confirmation, by this Agreement and by all acts already adopted by the JPASC in connection with this Agreement as of when this Agreement entered into force as set out in paragraph 4.

## Article 52

### **Transitional measures**

Contracting Parties other than the Commission that have not notified the Commission that this Agreement has entered into force for themselves, as set out in Article 51(4), may participate in the work of the JPASC, as observers, subject to such states signing the Agreement on participation in the work of the JPASC as an observer, attached as Annex III.

Contracting Parties other than the Commission that have not submitted to the Commission the Confirmation referred to in Article 51(4) shall not be taken into account for the purposes of reaching a common accord, qualified majority or simple majority under this Agreement.

## Article 53

### **Publication**

This Agreement and any amendments thereto shall be published in all official languages of those Contracting Parties that are Member States of the Union in the "C" Series of the *Official Journal of the European Union*.

IN WITNESS WHEREOF the undersigned, being duly authorised, have signed this Agreement.

Signed in [Luxembourg], on the [day] of [month], [year], in [insert], on the [day] of [month], 20XX, etc.:

1. For the European Commission: \_\_\_\_\_  
[to be completed], Director-General of the Directorate-General for Health and Consumers

2. [to be completed]

# ANNEXES

## Annex I

### **Declaration of absence of conflict of interest and protection of confidentiality to be given by members of the evaluation committee(s) as referred to in Article 37(5)**

Title of contract:

.....  
.....  
...

Reference:

(Call for tenders No):

.....  
.....  
...

I, the undersigned ....., having been [appointed to the evaluation committee] [given the responsibility of assessing exclusion and selection criteria and/or award criteria] for the above-mentioned contract, declare that I am aware of Article 57 of the Financial Regulation<sup>8</sup>, which states that:

*“1. Financial actors and other persons involved in budget implementation and management, including acts preparatory thereto, audit or control shall not take any action which may bring their own interests into conflict with those of the Union.*

*Where such a risk exists, the person in question shall refrain from such action and shall refer the matter to the authorising officer by delegation who shall confirm in writing whether a conflict of interests exists. The person in question shall also inform his or her hierarchical superior. Where a conflict of interests is found to exist, the person in question shall cease all activities in the matter. The authorising officer by delegation shall personally take any further appropriate action.*

*2. For the purposes of paragraph 1, a conflict of interests exists where the impartial and objective exercise of the functions of a financial actor or other person, as referred to in paragraph 1, is compromised for reasons involving family, emotional life, political or national affinity, economic interest or any other shared interest with a recipient.*

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<sup>8</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).

*3. The Commission shall be empowered to adopt delegated acts in accordance with Article 210 setting out what is likely to constitute a conflict of interests together with the procedure to be followed in such cases.”*

I hereby declare that, to my knowledge, I have no conflict of interest with the economic operators who have [applied to participate] [submitted a tender] for this contract, including persons or members of a consortium, or the subcontractors proposed.

I confirm that, if I discover during the evaluation that such a conflict exists, I will declare it immediately and resign from the committee.

I also confirm that I will keep all matters entrusted to me confidential. I will not communicate outside the committee any confidential information that is revealed to me or that I have discovered or any information relating to the views expressed during the evaluation. I will not make any adverse use of information given to me.

[I agree to abide by the terms of the Commission's Code of conduct for evaluators of which I have received a copy.]

Signed: .....

## **Annex II**

### **Confirmation of completion of national procedures for the approval of this Agreement or the absence of a need for such procedures as referred to in Article 51(4)**

**[Letter-head of authority representing a Contracting Party for the purposes of this  
Agreement]**

European Commission  
Director-General  
Directorate-General for Health & Consumers  
[Address]  
Fax: [xxx]

**Re: Confirmation of completion of national procedures for the approval of the Joint  
Procurement Agreement for the procurement of medical countermeasures or the  
absence of a need for such procedures in accordance with Article 51(4) of that  
Agreement**

Dear Sir/Madam

We refer to Article 51(4) of the above-mentioned Joint Procurement Agreement.

#### **EITHER**

We hereby notify you that our national procedures for the approval of the above-mentioned  
Joint Procurement Agreement were completed on [date].

#### **OR**

We hereby notify you that no national procedures are required for the approval of the above-  
mentioned Joint Procurement Agreement by [Name of Contracting Party].

Yours faithfully

[Name of Contracting Party]  
[National Authority]  
[Name, Function]  
[Address]  
Fax: [xxx]

### Annex III

#### **Agreement on participation in the work of the Joint Procurement Agreement Steering Committee as an observer referred to in the first paragraph of Article 52**

**[Letter-head of authority representing a Contracting Party for the purposes of this Agreement]**

European Commission  
Director-General  
Directorate-General for Health & Consumers  
[Address]  
Fax: [xxx]

**Re: Agreement on participation in the work of the Joint Procurement Agreement Steering Committee as an observer in accordance with the first paragraph of Article 52 of the Joint Procurement Agreement for the procurement of medical countermeasures**

Dear Sir/Madam

We refer to the first paragraph of Article 52 of the above-mentioned Joint Procurement Agreement entered into between the Commission and Member States of the European Union.

We understand that [name of the Contracting Party]'s participation in the work of the Joint Procurement Agreement Steering Committee pending the completion of the national procedures for [Member State] to approve the above-mentioned Agreement is subject to:

- [name of the Contracting Party]'s agreement to be bound by Article 5 to 6, Article 23, Articles 32 to **Error! Reference source not found.**8, Articles 39 to 43, Article 50 and the second paragraph of Article 52 of the above-mentioned Joint Procurement Agreement; and
- [name of the Contracting Party]'s compliance with the rules of procedure of the Joint Procurement Agreement Steering Committee including any measures promulgated under the said rules.

We hereby agree on behalf of [name of the Contracting Party] to be so bound and to be so compliant.

Yours faithfully

[Name of the Contracting Party]  
[National Authority]  
[Name, Function]  
[Address]  
Fax: [xxx]

## **Annex IV**

### **List of authentic linguistic versions of this Agreement referred to in Article 51(1)**

Spanish

Czech

Danish

German

Greek

English

French

Croatian

Italian

Lithuanian

Hungarian

Dutch

Portuguese

Slovak

Slovenian