

# ZAKON

## O POTVRĐIVANJU SPORAZUMA O ZAJEDNIČKIM NABAVKAMA MEDICINSKIH SREDSTAVA

### Član 1.

Potvrđuje se Sporazum o zajedničkim nabavkama medicinskih sredstava, kojem je Republika Srbija pristupila potpisivanjem u Beogradu, 21. aprila 2020. godine, u originalu na engleskom jeziku.

### Član 2.

Tekst Sporazuma o zajedničkim nabavkama medicinskih sredstava, u originalu na engleskom jeziku i u prevodu na srpski jezik glasi:

CPORAZUMENIE 3A СЪВМЕСТНА PROCEDURA 3A ВЪЗЛАГАНЕ HA  
ОВЩЕСТВЕНА ПОРЪЧКА 3A ДОСТАВЯНЕ HA MEDICINSKI MERKI ZA  
PROTIODEЙSTVIE

ACORDO DE CONTRATAÇÃO CONJUNTA DE CONTRAMEDIDAS MÉDICAS

DOHODA O SPOLEČNÉM ZADÁVACÍM ŘÍZENÍ NA LÉKAŘSKÁ PROTIOPATŘENÍ

AFTALE OM FÆLLES UDBUD VEDRØRENDE MEDICINSKE  
MODFORANSTALTNINGER

VEREINBARUNG ÜBER EIN GEMEINSAMES VERGABEVERFAHREN ZUR  
BESCHAFFUNG MEDIZINISCHER GEGENMASSNAHMEN

ÜHISHANKE KOKKULEPE MEDITSIINILISTE VASTUMEETMETE HANKIMISEKS

ΣΥΜΦΩΝΙΑ ΣΥΑΨΗΣ ΚΟΙΝΗΣ ΣΥΜΒΑΣΗΣ ΓΙΑ ΤΗΝ ΠΡΟΜΕΘΕΙΑ ΙΑΤΡΙΚΩΝ  
ΑΝΤΙΜΕΤΡΩΝ

JOINT PROCUREMENT AGREEMENT TO PROCURE MEDICAL  
COUNTERMEASURES

ACCORD DE PASSATION CONJOINTE DE MARCHÉ EN VUE DE L'ACQUISITION  
DE CONTRE-MESURES MÉDICALES

ACUERDO DE ADQUISICIÓN CONJUNTA DE CONTRAMEDIDAS MÉDICAS

SPORAZUM O ZAJEDNIČKOJ JAVNOJ NABAVI ZA NABAVU MEDICINSKIH  
PROTUMJERA

ACCORDO DI AGIUDICAZIONE CONGIUNTA PER L'ACQUISTO D'  
CONTROMISURE MEDICHE

MEDICINISKO PRETLÍDZEK ĽU KOPÍGĀ IEPIRKUMA NOLÍGUMS

BRNDRO VIEŠOJO PIRKIMO SUSITARIMAS DĒL MEDICININIŲ REAGAVIMO  
PRIEMONIŲ ĮSIGIJIMO

KÖZÖS KÖZBESZERZÉSI MEGÁLLAPODÁS EGÉSZSÉGÜGYI  
ELLENINTÉZKEDÉSEK BESZERZÉSÉRE

GEZAMENLIJKE AANBESTEDINGSOVEREENKOMST VOOR DE AANKOOP VAN  
MEDISCHE TEGENMAATREGELEN

FTEHIM TA' AKKWIST KONGUNT GHAI.L-AKKWIST TA' KONTROMIŽURI MEDIÓ

POROZUMIENIE DOTYCZĄCE WSPÓLNEGO UDZIELANIA ZAMÓWIEŃ NA  
ZAKUP MEDYCZNYCH ŚRODKÓW ZAPOBIEGAWCZYCH

ACORD DE ACHIZIȚIE COMUNĂ PENTRU ACHIZIȚII PUBLICE DE  
CONTRAMĂSURI MEDICALE

SPORAZUM O SKUPNI ODDAJI NAROČIL ZA ZDRAVSTVENE PROTIUKREPE

DOHODA O SPOLOČNOM OBSTARÁVANÍ ZDRAVOTNÍCKYCH PROTIOPATRENÍ

SOPIMUS LÄÄKETIETEELLISTEN VASTATOIMIEN YHTEISHANKINNASTA

AVTAL OM GEMENSAM UPPHANDLING AV MEDICINSKA MOTÅTGÄRDER

This Joint Procurement Agreement (the "Agreement") is made by and between the following Contracting Parties:

the European Commission (the "Commission"), which is represented for the purposes of this Agreement by the European Commissioner for Health, Tonio Borg and the Director-General of the Directorate-General for Health and Consumers, Paola Testori Coggi

and

the following Member States of the European Union:

1. Kingdom of Belgium
2. Republic of Bulgaria
3. Czech Republic
4. Kingdom of Denmark
5. Federal Republic of Germany
6. Republic of Estonia
7. Ireland
8. Hellenic Republic
9. Kingdom of Spain
10. French Republic
11. Republic of Croatia
12. Italian Republic
13. Republic of Cyprus
14. Republic of Latvia
15. Republic of Lithuania
16. Grand Duchy of Luxembourg
17. Hungary
18. Republic of Malta
19. Kingdom of the Netherlands
20. Republic of Austria
21. Republic of Poland
22. Portuguese Republic
23. Romania
24. Republic of Slovenia
25. Slovak Republic
26. Republic of Finland
27. Kingdom of Sweden
28. United Kingdom of Great Britain and Northern Ireland

## 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.
- (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

<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/lsa/118254.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/118254.pdf)

<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).

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)
- 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)

---

<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).

## 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

### **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

<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).

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.

## 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.*

*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.

---

<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).

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

Sъstaveno v Luksemburg na dvadeseti юни dve hiljdi i četirinadeseta godina.

Hecho en Luxemburgo, el veinte de junio de dos mil catorce.

V Lucemburku dne dvacátého června dva tisíce čtrnáct.

Udfærdiget i Luxembourg den tyvende juni to tusind og fjorten.

Geschehen zu Luxemburg am zwanzigsten Juni zweitausendvierzehn.

Kahe tuhande neljateistkümnenda aasta juunikuu kahekümnendal päeval Luxembourgis.

Έγινε στο Λουξεμβούργο, στις είκοσι Ιουνίου δύο χιλιάδες δεκατέσσερα.

Done at Luxembourg on the twentieth day of June in the year two thousand and fourteen.

Fait à Luxembourg, le vingt juin deux mille quatorze.

Arna dhéanamh i Luksamburg, an fichiú lá de Mheitheamh an bhliain dhá mhíle agus a ceathair déag.

Sastavljeno u Luxembourgu dvadesetog lipnja dvije tisuće četrnaeste.

Fatto a Lussemburgo, addì venti giugno duemilaquattordici.

Luksemburgā, divi tūkstoši četrpadsmitā gada divdesmitajā jūnijā.

Priimta dū tūkstančiai keturioliktu metu birželio dvidešimtą dieną Liuksemburge.

Kelt Luxembourgban, a kétézer-tizenegyedik év június havának huszadik napján.

Magħmul fil-Lussemburgu, fl-ġħoxrin jum ta' Ĝunju tas-sena elfejn u erbatax.

Gedaan te Luxemburg, de twintigste juni tweeduizend veertien.

Sporządzono w Luksemburgu dnia dwudziestego czerwca roku dwa tysiące czternastego.

Feito em Luxemburgo, em vinte de junho de dois mil e catorze.

Întocmit la Luxemburg la douăzeci iunie două mii paisprezece.

V Luxemburgu dvadsiateho júna dvetisicštrnást’.

V Luxemburgu, dne dvajsetega junija leta dva tisoč štirinajst.

Tehty Luxemburgissa kahdentenakymmenentenä päivänä kesäkuuta vuonna kaksituhattaneljätoista.

Som skedde i Luxemburg den tjugonde juni tjugohundrafjorton.

Za Komisiјта  
Por la Comisión  
Za Komisi  
På Kommissionens vegne  
Für die Kommission  
Komisjoni nimel  
Για την Επιτροπή<sup>1</sup>  
For the Commission  
Par la Commission  
Per la Commissione  
Komisijas vārdā —  
Komisijos vardu  
A Bizottság részéről  
Għall-Kummissjoni  
Voor de Commissie  
W imieniu Komisji  
Pela Comissão  
Pentru Comisie  
Za Komisiu  
Za Komisijo  
Komission puolesta  
På kommissionens vägnar

Voor het Koninkrijk België

Pour le Royaume de Belgique

Für das Königreich Belgien

Za Republika Bъlgaria

Za Českou republiku

For Kongeriget Danmark

Für die Bundesrepublik Deutschland

Eesti Vabariigi nimel

Thar cheann Na hÉireann  
For Ireland

Για την Ελληνική Δημοκρατία

Por el Reino de España

Pour la République française

Za Republiku Hrvatsku

Per la Repubblica italiana

Για την Κυπριακή Δημοκρατία

Latvijas Republikas vārdā –

Lietuvos Respublikos vardu

Pour le Grand-Duché de Luxembourg

Magyarország részéről

Għar-Repubblika ta' Malta

Voor het Koninkrijk der Nederlanden

Für die Republik Österreich

W imieniu Rzeczypospolitej Polskiej

Pela Repúbliga Portuguesa

Pentru România

Za Republiko Slovenijo

Za Slovenskú republiku

Soumen tasavallan puolesta  
För Republiken Finland

För Konungariket Sverige

For United Kingdom of Great Britain and Northern Ireland

For the Kingdom of Norway

For Iceland

Für das Fürstentum Liechtenstein

For the Republic of Serbia

Minister of Finance

Mr Siniša Mali

April 21, 2020

Belgrade

For Montenegro

For the Republic of North Macedonia

For the Republic of Albania

For Bosnia and Herzegovina

For Kosovo\*

\* This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence



Brussels, 5.3.2015  
C(2015) 1407 final

## CORRIGENDUM

**to Commission Decision C(2014)2258 final of 10 April 2014 on approval of the Joint  
Procurement Agreement to procure medical countermeasures pursuant to  
Decision 1082/2013/EU**

EN

EN

## CORRIGENDUM

**to Commission Decision C(2014)2258 final of 10 April 2014 on approval of the Joint Procurement Agreement to procure medical countermeasures pursuant to Decision 1082/2013/EU**

In Article 7(3) of the Annex

*for:* '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.'

*read:* '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 4, a second vote shall be organised at a subsequent meeting. By way of derogation from paragraph 2, 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 4, 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.

'In Article 7(4) of the Annex

*for:* '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.'

*read:* '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 paragraphs 2 and 3 can be held at the same meeting.'

In Article 7(5) of the Annex

*for:* '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.'

*read:* 'Notwithstanding the first subparagraph of paragraph 1, paragraphs 2 and 3 shall not apply where the unanimous agreement of the members of a Steering Committee is required under this Agreement.'

In the first subparagraph of Article 25(5) of the Annex

*for:* '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.'

*read:* '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.'

In the first subparagraph of Article 26(4) of the Annex

*for:* '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.'

*read:* '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.'

In the first bullet point of Annex III of the Annex

*for:* '[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.'

*read:* '[name of the Contracting Party]'s agreement to be bound by Article 5 to 6, Article 23, Articles 32 to 38, Articles 39 to 43, Article 50 and the second paragraph of Article 52 of the above-mentioned Joint Procurement Agreement.'

## **SPORAZUM O ZAJEDNIČKIM NABAVKAMA MEDICINSKIH SREDSTAVA**

Ovaj Sporazum o zajedničkim nabavkama („Sporazum“) sačinjen je od strane i između sledećih ugovornih strana:

Evropske komisije („Komisija“), koju za potrebe ovog Sporazuma zastupa Evropski komesar za zdravlje, Tonio Borgi direktor Generalnog direktorata za zdravlje i zaštitu potrošač Paola Testori Kodži

i

sledećih država članica Evropske unije:

1. Kraljevina Belgija
2. Republika Bugarska
3. Češka Republika
4. Kraljevina Danska
5. Savezna Republika Nemačka
6. Republika Estonija
7. Irska
8. Republika Grčka
9. Kraljevina Španija
10. Republika Francuska
11. Republika Hrvatska
12. Republika Italija
13. Republika Kipar
14. Republika Letonija
15. Republika Litvanija
16. Veliko vojvodstvo Luksemburg
17. Mađarska
18. Republika Malta
19. Kraljevina Holandija
20. Republika Austrija
21. Republika Poljska
22. Republika Portugalija
23. Rumunija
24. Republika Slovenija
25. Slovačka Republika
26. Republika Finska
27. Kraljevina Švedska
28. Ujedinjeno Kraljevstvo Velike Britanije i Severne Irske

## PREAMBULA

S OBZIROM NA:

- (1) Drugi podstav člana 168(1) Ugovora o funkcionisanju Evropske unije („Ugovor“) predviđa „delovanje Unije koje će dopunjavati nacionalne politike, i biće usmereno na poboljšanje javnog zdravlja, sprečavanje bolesti. Takva delovanja obuhvataju borbu protiv ozbiljnih prekograničnih pretnji po zdravlje“.
- (2) Prekogranične pretnje, poput pandemijskog gripa, mogu se suzbiti vakcinacijom, sprečavajući potencijalno tešku bolest, pa čak i smrt.
- (3) U svojim Zaključcima od 13. septembra 2010<sup>1</sup>, Savet je pozvao Komisiju da podnese izveštaj i razvije mehanizam za zajedničku nabavku vakcina i antivirusnih lekova koji bi omogućili državama članicama da, na dobrovoljnoj osnovi, usvoje zajedničke pristupe za pregovaranje ugovora sa industrijom, što bi jasno rešilo pitanja kao što su odgovornost, dostupnost i cena lekova, kao i poverljivost.
- (4) Na sastanku Saveta za pitanja zapošljavanja, socijalne politike, zdravlja i zaštite potrošača održanom 6. i 7. decembra 2010<sup>2</sup>, velika većina država članica složila se da bi najprikladnije sredstvo za sprovođenje zajedničkih postupaka nabavke za pandemijske vakcine bilo razvijanje okvirnih ugovora koje države članice mogu sklopiti na dobrovoljnoj osnovi.
- (5) Član 5(1) Odluke br. 1082/2013/EU Evropskog parlamenta i Saveta od 22. oktobra 2013<sup>3</sup> proširio je ovaj pristup izvan vakcina i antivirusnih lekova protiv pandemijskog gripa. U skladu s tim članom, institucije Unije i države članice mogu se uključiti u postupak zajedničke nabavke u cilju prethodne kupovine medicinskih sredstava za ozbiljne prekogranične pretnje po zdravlje.
- (6) Očekuje se da će zajednička nabavka ojačati kupovnu moć ugovornih strana i osigurati pravedan pristup medicinskim sredstvima protiv ozbiljnih prekograničnih pretnji po zdravlje.
- (7) Zaključivanje Sporazuma o zajedničkim nabavkama ne podrazumeva nikakvu obavezu za ugovorne strane da naknadno učestvuju u postupcima nabavke pokrenutim radi sticanja konkretnih medicinskih sredstava na osnovu tog Sporazuma.
- (8) U svrhu nabavke medicinskih sredstava protiv ozbiljnih prekograničnih pretnji po zdravlje, ugovorne strane su odlučile da se uključe u zajedničko delovanje, u smislu trećeg podstava člana 104(1) Uredbe (EU, Euratom) br. 966/2012 Evropskog parlamenta i Saveta<sup>4</sup>.
- (9) Ugovorne strane nameravaju da sprovode zajedničko delovanje, dodeljivanjem ugovora za kupovinu medicinskih sredstava protiv ozbiljnih prekograničnih pretnji po zdravlje sledeći jedan ili više postupaka zajedničke nabavke u smislu Delegirane

---

<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/isa/118254.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/isa/118254.pdf)

<sup>3</sup>Odluka br. 1082/2013/EU Evropskog parlamenta i Saveta od 22. oktobra 2013. o ozbiljnim prekograničnim pretnjama zdravlju i stavljanju van snage Odluke br. 2119/98/EK (SL L 293, 5.11.2013, str. 1).

<sup>4</sup> Uredba (EU, Euratom) br. 966/2012 Evropskog parlamenta i Saveta od 25. oktobra 2012. o finansijskim pravilima koja se primenjuju na opšti budžet Unije i stavljanju van snage Uredbe Saveta (EK, Euratom) br. 1605/2002 (SL L 298, 26.10.2012, str. 1).

uredbe Komisije (EU) br. 1268/2012<sup>5</sup>, kako je predviđeno članom 5 Odluke br. 1082/2013/EU.

(10) Ništa u ovom Sporazumu ne utiče na prava i obaveze država članica i Komisije prema Ugovorima, i postizanje ciljeva Evropske unije, naročito u oblasti javnog zdravlja,

#### UGOVORNE STRANE SU SE SPORAZUMELE

o dolenavedenim uslovima uključujući sledeće Anekse:

**Aneks I -** Izjava o odsustvu sukoba interesa i zaštiti poverljivosti koju treba da da(ju) član(ovi)odbora za procenu, kako se navodi u članu 37(5)

**Aneks II -** Potvrda o završetku nacionalnih procedura za odobrenje ovog Sporazuma ili odsustvo potrebe za takvim procedurama kako se navodi u članu 51(4)

**Aneks III -** Sporazum o učešću u radu Upravnog odbora Sporazuma o zajedničkim nabavkama u svojstvu posmatrača kako se navodi u prvom stavu člana 52

**Aneks IV -** Spisak verodostojnih jezičkih verzija ovog Sporazuma kako se navodi u članu 51(1)

---

<sup>5</sup>Delegirana uredba Komisije (EU) br. 1268/2012 od 29. oktobra 2012. o pravilima primene Uredbe (EU, Euratom) br. 966/2012 Evropskog parlamenta i Saveta o finansijskim pravilima koja se primenjuju na opšti budžet Unije (SL L 362, 31.12.2012, str. 1).

**Glava I**  
**OPŠTE ODREDBE**  
**Član 1**

**Predmet Sporazuma**

1. Ovaj Sporazum predviđa mogućnost ugovornih strana da nabave medicinska sredstva dodeljivanjem ugovora na osnovu postupka zajedničke nabavke.
2. Ovaj Sporazum utvrđuje praktične modalitete koji regulišu postupak zajedničke nabavke u skladu sa trećim stavom člana 133 Pravila primene.
3. Ovaj Sporazum takođe obuhvata dodatna pitanja kao što su:
  - (i) upravljanje okvirnim ugovorima
  - (ii) vođenje bilo kojeg sudskog postupka koji proizlazi iz postupka zajedničke nabavke ili okvirnih ugovora ili iz situacije nepoštovanja ovog Sporazuma; i
  - (iii) sporazumno rešavanje bilo kakvih nesuglasica između ugovornih strana.
4. Lice koje nije strana u ovom Sporazumu nema pravo da sprovodi ili uživa bilo koja prava ili ostvaruje koristi predviđene bilo kojim članom ovog Ugovora.
5. Ovaj Sporazum ne dovodi u pitanje pravo ugovornih strana da sprovode postupak nabavke van ovog Sporazuma, čak i kada takvi postupci uključuju nabavku medicinskih sredstava koja su predmet postupka zajedničke nabavke ili okvirnog ugovora ili uključuju privredne subjekte ili ugovarače koji su konkurisali ili su potpisali okvirni ugovor u skladu sa postupkom zajedničke nabavke prema ovom Sporazumu.

**Član 2**

**Značenje pojmova**

1. Svi uslovi u ovom Sporazumu koji proizlaze ili su definisani u Finansijskoj uredbi ili Pravilima primene, imaju isto značenje kao u tim aktima.

Za potrebe ovog Sporazuma:

- (a) „medicinska sredstva“ znači bilo koji lek, medicinski uređaj i druga roba ili usluge usmerene na borbu protiv ozbiljnih prekograničnih pretnji po zdravlje, kako se navodi u Odluci br. 1082/2013/EU;
- (b) „Ugovor“ označava Ugovor o funkcionisanju Evropske unije;
- (v) „okvirni ugovor“ označava okvirni ugovor, kako se navodi u članu 101(2) Finansijske uredbe i članovima 121 i 122 Pravila primene, te proizlazi iz postupka zajedničke nabavke sprovedene u skladu sa ovim Sporazumom a potписан je od strane ugovarača i jedne ili više ugovornih strana;
- (g) „Ugovorna strana“ označava stranu koja je potpisala ovaj Sporazum;
- (d) „privredni subjekt“ označava svako fizičko ili pravno lice ili javni subjekt koji nudi medicinska sredstva na tržištu;
- (đ) „ugovarač“ označava fizičko ili pravno lice sa kojim je ugovor o nabavci zaključen nakon postupka nabavke sprovedenog u skladu sa ovim Sporazumom;
- (e) „Finansijska uredba“ označava Uredbu br. 966/2012 (EU, Euratom) Evropskog parlamenta i Saveta od 25. oktobra 2012. o finansijskim pravilima primenjivim na opšti budžet Unije kojom se stavlja van snage Uredba Komisije (EK, Euratom) br. 1605/2002;
- (ž) „Pravila primene“ označavaju delegiranu Uredbu Komisije (EU) br. 1268/2012 od 29. oktobra 2012. o pravilima primene Uredbe (EU, Euratom) br.

966/2012 Evropskog parlamenta i Saveta o finansijskim pravilima koja se primenjuju na opšti budžet Unije;

(z) „direktan ugovor“ označava javni ugovor, kako se navodi u članu 101(1) Finansijske uredbe, koji je rezultat zajedničkog postupka nabavke sprovedene u skladu sa ovim Sporazumom i potписан je od strane ugovarača i jedne ili više Ugovornih strana(e);

(i) „poseban ugovor“ označava poseban ugovor iz člana 122 Pravila primene, zaključen između jedne ugovorne strane i ugovarača na osnovu okvirnog ugovora;

(j) „ugovorna strana koja učestvuje“ označava ugovornu stranu koja učestvuje u postupku zajedničke nabavke za određena medicinska sredstva sprovedenom u skladu sa ovim Sporazumom;

(k) „Upravni odbori“ označavaju Upravni odbor Sporazuma o zajedničkim nabavkama i jedan ili više upravnih odbora za određen postupak nabavke;

(l) „osoblje“ označava svako lice koje radi za ugovornu stranu;

(lj) „rukovanje“ informacijama ili dokumentima označava generisanje, obrađivanje, skladištenje, prenošenje ili uništavanje informacija ili dokumenata;

(m) „lica koja rade u vezi sa ovim Sporazumom“ znači bilo koje lice koje radi za ugovornu stranu u vezi sa ovim Sporazumom bez obzira na to da li je zaposlena od strane te ugovorne strane ili ne;

(n) „Sud pravde“ označva Sud pravde Evropske unije;

(nj) „treća strana“ označava bilo koje fizičko ili pravno lice, javni subjekt ili grupu njih koja nisu potpisnici ovog Sporazuma.

### Član 3

#### **Pravila koja regulišu postupak zajedničke nabavke**

1. Na ovaj Sporazum primenjuje se prvi stav člana 133 Pravila primene. U slučaju sukoba, nad ovim sporazumom preovladava Finansijska uredba i Pravila primene.

2. Sledеće odredbe se primenjuju na informacije koje se koriste u okviru ovog Sporazuma:

- (a) Član 339 Ugovora o obavezi čuvanja profesionalne tajne;
- (b) Član 57 Finansijske uredbe;
- (v) Član 32 Pravila primene o odsustvu sukoba interesa;
- (g) drugi podstav člana 113(2) Finansijske uredbe o neobjavljinju određenih informacija proisteklih iz postupka nabavke; i
- (d) Član 155(3) Pravila primene o tajnosti ponuda.

3. Ne dovodeći u pitanje prvi stav člana 133 Pravila primene, svaka država članica ostaje odgovorna za poštovanje bilo kojih proceduralnih zahteva iz svog nacionalnog zakona.

### Član 4

#### **Ovlašćenja data Komisiji u ime ugovernih strana**

1. Kada Komisija doneše obavezujući akt prema i u skladu sa ovim Sporazumom, taj akt obavezuje sve ugovorne strane, ili, gde je to primenljivo, samo one ugovorne strane na koje se taj akt odnosi.

2. U skladu sa ovim Sporazumom, svaka ugovorna strana ovlašćuje Komisiju da deluje u njeni ime u skladu sa pravom Unije u:

(a) vođenju postup(a)ka zajedničke nabavke, uključujući dodeljivanje okvirnih ili direktnog(ih) ugovora;

(b) upravljanju okvirnim ugovorom(ima), uključujući potpis bilo koje izmene nesuštinske prirode, u skladu sa članom 122 Pravila primene.

Posebni ugovori nakon postupka zajedničke nabavke sprovedene u skladu sa ovim Sporazumom, zaključuju se i njima se upravlja na individualnoj osnovi od strane svake ugovorne strane, u skladu sa članom 27.

3. Ugovorne strane ovlašćuju Komisiju da deluje kao njihov jedini predstavnik u pokretanju ili odbrani bilo kojeg sudskog postupka koji je ugovarač pokrenuo na osnovu okvirnog ugovora, osim bilo kojeg sudskog postupka pokrenutog protiv ugovorne strane na osnovu posebnog ugovora zasnovanog na okvirnom ugovoru zaključenom u skladu sa članom 122 Pravila primene.

Komisija će, kao jedini predstavnik ugovornih strana, tražiti mišljenje relevantnog Upravnog odbora za određeni postupak nabavke („UOOPN“) o vođenju bilo kojeg sudskog postupka obuhvaćenog ovim stavom, prvom prilikom, u skladu sa članom 7 ovog Sporazuma.

4. Ugovorne strane ovlašćuju Komisiju da deluje kao njihov jedini zastupnik u pokretanju bilo kojeg sudskog postupka protiv ugovarača na osnovu okvirnog ugovora, osim bilo kojeg sudskog postupka na osnovu posebnog ugovora zasnovanog na okvirnom ugovoru zaključenom u skladu sa članom 122 Pravila primene.

Ovlašćenje Komisije iz prvog podstava podleže odobrenju od strane nadležnog UOOPN-a kada je u pitanju pokretanje takvih sudskih postupaka u skladu sa članom 7 na predlog ugovorne strane koja učestvuje ili Komisije. Nakon toga, Komisija će tražiti mišljenje nadležnog UOOPN-a o vođenju svih sudskih postupaka obuhvaćenih ovim stavom, prvom prilikom, u skladu sa članom 7 ovog Sporazuma.

5. Komisija može da reši sve sporove, sudske postupke pokrenute u skladu sa stavovima 3 ili 4 nakon odobrenja nadležnog UOOPN-a na osnovu predloga u tom smislu ugovorne strane koja učestvuje ili Komisije, u skladu sa članom 7 ovog Sporazuma.

**Glava II**  
**ORGANIZACIJA**  
**Poglavlje I**  
**Upravni odbor**  
**Član 5**  
**Dužnosti**

1. Upravni odbor Sporazuma o zajedničkim nabavkama (UOSZN) se ovim uspostavlja. UOSZN odgovoran je za vođenje pitanja koja se odnose na predmet ovog Sporazuma, uključujući:

(a) odluke, prvenstveno o vrsti medicinskih sredstava čija će se nabavka odvijati pod okriljem ovog Sporazuma, kao i o vremenskom redosledu organizovanja nabavki;

(b) sve sudske postupke u okviru postupka zajedničke nabavke koji se tiču svih ugovornih strana;

(v) postupak neophodan za rešavanje nepoštovanja ovog Sporazuma od ugovorne strane;

- (g) sporazumno rešavanje nesuglasica između dve ili više ugovornih strana;
- (d) amandmane na ovaj Sporazum, u skladu sa članom 46.

U skladu sa ovim stavom, kada UOSZN usvoji obavezujući akt, taj akt je obavezujući za sve ugovorne strane.

2. Ugovorne strane koje učestvuju uspostaviće UOOPN koji će biti odgovoran za pitanja koja se odnose na određenu nabavku, uključujući:

- (a) poseban postupak zajedničke nabavke;
- (b) sve sudske postupke u sklopu okvirnog ugovora;
- (v) definisanje i primenu kriterijuma za raspodelu u skladu sa članom 17(1);
- (g) privremena odstupanja od kriterijuma za raspodelu u skladu sa članom 17(2).

U skladu sa ovim stavom, kada UOOPN usvoji obavezujući akt, taj akt je obavezujući za ugovorne strane koje učestvuju.

3. Upravni odbor daje mišljenja i odobrenja, u skladu sa članom 7, kako je predviđeno ovim Sporazumom.

4. Upravni odbor glasa na osnovu predloga Komisije, osim ako je ovim Sporazumom drugačije predviđeno.

## Član 6

### Sastav i članstvo

1. Upravni odbori su sastavljeni od po jednog predstavnika svake ugovorne strane. Člana može odmeniti zamenik.

Samo službeni predstavnici ugovorne strane mogu biti članovi Upravnih odbora ili njihovi zamenici.

2. Članovima Upravnih odbora i njihovim zamenicima mogu, u skladu sa njihovim pravilnicima, pomagati savetnici.

3. Sastancima Upravnih odbora predsedava predstavnik Komisije ili njegov zamenik („predsedavajući“).

Kada se na sastanku ne obraća u svojstvu predsedavajućeg, predstavnik Komisije će istaći da iznosi stav Komisije kao ugovorne strane.

4. Komisija će osnovati sekretarijat Upravnih odbora.

5. Ugovorne strane će, u roku od četrnaest dana od dana potpisivanja ovog Sporazuma, dostaviti Komisiji informacije o identitetu i kontakt podatke svojih članova u UOSZN, njihovih zamenika i savetnika koji im pomažu.

Ugovorne strane koje žele da učestvuju u zajedničkoj nabavci određenih medicinskih sredstava će, u roku od četrnaest dana od donošenja odluke UOSZN po ovom pitanju, dostaviti Komisiji informacije o identitetu i kontakt podatke svojih članova u UOOPN, njihovih zamenika i savetnika koji im pomažu.

Komisija će sastaviti listu osoba pomenutih u drugom podstavu u skladu sa informacijama dobijenim od ugovornih strana. Ugovorne strane će se međusobno obaveštavati o svim promenama koje se tiču identiteta i/ili kontakt podataka ovih osoba.

6. Upravni odbori će, prostom većinom glasova svojih članova, a na osnovu predloga predsedavajućeg, usvojiti Prvilnik.

7. Predsedavajući će, u roku od 14 dana od sastanka UOSZN ili UOOPN, dostaviti članovima odgovarajućeg odbora zapisnik sa sastanka.

## Član 7

### **Procedure za davanje mišljenja i odobrenja Upravnih odbora**

1. Kada se ovim Sporazumom zahteva od UOSZN ili UOOPN da daju mišljenje ili odobrenje na predlog koji je pred njega stavljen, članovi odgovarajućeg Upravnog odbora nastoje da postignu zajednički dogovor.

Uzdržanost članova bilo UOSZN ili UOOPN neće sprečiti odgovarajući Upravni odbor da postigne zajednički dogovor.

Kada članovi UOSZN ili UOOPN ne mogu dostići zajednički dogovor, oni će glasati. Predsedavajući određuje kada će pozvati na glasanje.

2. Mišljenje Upravnog odbora će biti usvojeno zajedničkim dogovorom ili prostom većinom glasova njegovih članova.

Mišljenje strane Upravnog odbora na dostavljeni predlog u skladu sa ovim Sporazumom nije obavezujući za Komisiju. Međutim, prilikom usvajanja predloga, Komisija će u najvećoj mogućoj meri uzeti u obzir dostavljeno mišljenje.

Smatraće se da je Upravni odbor odobrio predlog ukoliko je on usvojen zajedničkim dogovorom ili kvalifikovanom većinom njegovih prisutnih ili zastupljenih članova.

Kvalifikovana većina je definisana kao 55% prisutnih ili zastupljenih članova UOSZN koji predstavljaju ugovorne strane koje obuhvataju najmanje 65% ukupnog iznosa medicinskih sredstava obuhvaćenih zajedničkom nabavkom.

Za predloge o pitanjima koja se tiču samo UOOPN-a, kvalifikovana većina će biti definisana kao 55% njegovih članova i predstavljenih ugovornih strana koje obuhvataju najmanje 65% ukupnih stvarnih troškova, ili ako stvarni trošak još nije poznat, procenjeni trošak medicinskih sredstava koje pokrivaču dotične ugovorne strane.

3. Ako se predlog ne usvoji kvalifikovanom većinom prisutnih ili zastupljenih članova relevantnog Upravnog odbora, onda se, ne dovodeći u pitanje stav 5, organizuje drugo glasanje na narednom sastanku. Izuzetno od stava 3, predlog će se smatrati odobrenim od strane Upravnog odbora ako je izglasani prostom većinom prisutnih ili zastupljenih članova koji glasaju u ime ugovornih strana čije učešće u proceduri iznosi minimum 50% ukupnih stvarnih troškova (ili, ukoliko stvarni troškovi još nisu poznati, procenjenih troškova) medicinskih sredstava koje pokrivaču postupak zajedničke nabavke, ili, tamo gde je primenjivo, pokrivaču Ugovorne strane u UOOPN.

Ako predlog ne može biti usvojen prostom većinom, onda će, ne dovodeći u pitanje stav 5, treće glasanje biti održano na narednom sastanku. Ako prosta većina, onako kako je definisana prvim podstavom, ponovo ne može da se postigne, predlog će se smatrati odobrenim osim ako postoji kvalifikovana većina protiv istog.

4. Kada je hitno potrebno odobrenje predloga od strane Upravnog odbora, on će se održati telefonskim putem ili na drugi odgovarajući način komunikacije na daljinu, a uzastopna glasanja iz stava 3 mogu se održati na istoj sednici.

5. Bez obzira na prvi podstav stava 1, stavovi 3 i 4 ne primenjuju se ako se ovim Sporazumom zahteva jednoglasan dogovor članova Upravnog odbora.

## Poglavlje II

### **Odbori za procenu**

## Član 8

## **Dužnosti**

1. Ne dovodeći u pitanje treći podstav člana 158(1) Pravila primene, Komisija će uspostaviti odbor za procenu radi procene zahteva za učešće ili tendera u smislu člana 111(5) Finansijske uredbe.
2. Bez obzira na stav 1, Komisija može imenovati dva odvojena odbora za procenu:
  - (a) odbor za odabir zahteva za učešće ili ponuda na osnovu kriterijuma za isključenje i izbor; i
  - (b) odbor za procenu ponuda na osnovu kriterijuma za dodelu.

## **Član 9**

### **Sastav i postupak imenovanja**

1. Odbor(i) za procenu će se sastojati od:
  - (a) ne više od tri lica određena od strane Komisije, u skladu sa prvim podstavom člana 158(2) Pravila primene, i u slučajevima gde Komisija nije zainteresovana za konkretan zahtev za učešće ili ponudu;
  - (b) ne više od pet osoba od onih koje su imenovali ugovorne strane koje učestvuju, osim Komisije, u skladu sa procedurom utvrđenom u stavu 2. Ova lica ne smeju biti ista kao lica imenovana od strane Komisije.

Kako je određeno članom 8(2), ista osoba može biti član oba odbora za procenu.

Odborom za procenu predsedavaće službenik Komisije koji je član nadležnog odbora.

2. Na osnovu zahteva Komisije, sve ugovorne strane koje učestvuju imenovaće jednog kandidata za članstvo u odboru za procenu dostavljajući predsedavajućem popunjeno *pro-forma* obrazac za prijavljivanje praćen podacima o identitetu, obrazovanju, profesionalnim kvalifikacijama i iskustvu imenovanog kandidata u UOOPN preko predsedavajućeg a u skladu sa *pro-forma* obrascem. *Pro-forma* obrazac usvaja Komisija, nakon odobrenja UOOPN u skladu sa procedurom naznačenom u članu 7.

Kandidat može biti nominovan samo od stane jedne ugovorne strane koja učestvuje. Svaku nominaciju mora podržati druga ugovorna strana koja učestvuje.

Komisija može odbiti imenovanje kandidata nominovanog za članstvo u odboru za procenu kada postoje osnove za pretpostavku da je kandidat u sukobu interesa u smislu člana 57 Finansijske uredbe. U tom slučaju, ugovorna(e) stana(e) razmotriće nominovanje drugog kandidata.

3. Komisija će, na odobrenje UOOPN predložiti listu članova nominovanih od stane ugovornih strana koje učestvuju.

U slučaju kada:

- a) ne postoji više od pet ugovornih strana koje učestvuju, osim Komisije, Komisija će predložiti sve nominovane kandidate;
- b) postoji šest ili više ugovornih strana koje učestvuju, osim Komisije, Komisija će predložiti listu od pet kandidata.

UOOPN će oceniti podobnost predloženih kandidata. U roku od 14 dana od dana kada je predlog Komisije poslat, bilo koji član UOOPN može od Komisije zahtevati sledeće:

- (a) razgovor sa bilo kojim nominovanim kandidatom;
- (b) da zahteva dodatne informacije od nominovanih kandidata ili ugovorne(ih) strane(a) koje nominuju;
- (v) da zahteva dostavljanje informacija o identitetu, obrazovanju, profesionalnim kvalifikacijama i iskustvu kandidata nominovanih u skladu sa stavom 2.

Komisija će imenovati članove odbora za procenu iz stava 1(b) nakon odobrenja UOOPN, u skladu sa članom 7.

4. Članovi odbora za procenu neće učestvovati u njegovom radu do potpisivanja izjave o nepostojanju sukoba interesa i izjave o poverljivosti („izjava“) iz prvog podstava člana 37(5) u odnosu na ugovornu stranu koja ih je imenovala ili nominovala ili njihovog poslodavca.

Ne dovodeći u pitanje treći podstav ovog stava, kada član odbora za procenu nije zaposlen kod ugovorne strane, ugovorna strana će sa pomenutim poslodavcem sklopiti ugovorni aranžman kojim poslodavac preuzima punu odgovornost za eventualno kršenje izjave u odnosu na ugovornu stanu.

Svaka ugovorna strana je odgovorna prema svakoj drugoj ugovornoj strani za osiguranje poštovanja ovog stava i za izmirivanje svake eventualne štete nanete kršenjem Izjave od strane člana odbora za procenu kojeg je ta ugovorna strana imenovala ili nominovala.

5. Komisija će sastaviti listu članova odbora za procenu. Komisija će, takođe, čuvati potpisane primerke Izjave.

6. Članovi odbora za procenu predloženi od ugovornih strana koje učestvuju biće imenovani *ad personam*. Tokom obavljanja svojih zadataka oni neće tražiti ili primati instrukcije od institucija, tela, kancelarija ili agencija Unije, vlada bilo koje ugovorne strane ili bilo kog drugog tela. Ugovorne strane se obavezuju da će poštovati ovo načelo i da neće nastojati da utiču na članove odbora za procenu u ispunjivanju njihovih zadataka.

Članovi odbora za procenu ne učestvuju u bilo kojoj raspravi, postizanju zajedničkog dogovora ili glasanju na sastanku UOOPN, na osnovu bilo kog pisanih tragova iz člana 10(3) kojem su doprineli.

7. Članovi odbora za procenu će podneti ostavku predsedavajućem UOOPN, sa otkaznim rokom od sedam dana, ukoliko nisu u mogućnosti da poštuju Izjavu ili da na drugi način obavljaju svoje dužnosti.

8. Svaki član UOOPN može zahtevati razrešenje člana odbora za procenu zbog kršenja Izjave ili ukoliko na drugi način nije u mogućnosti da obavlja svoje dužnosti. Za zahtev za razrešenje člana potrebno je odobrenje UOOPN-a u skladu sa članom 7.

9. Nakon ostavke ili razrešenja člana odbora za procenu kojeg je imenovala ugovorna strana koja učestvuje, ona će imenovati novog člana u skladu sa postupkom utvrđenim u stavovima 2 i 3. Nakon ostavke ili razrešenja člana odbora za procenu od strane Komisije, Komisija će odrediti novog člana.

## Član 10

### Procedura

1. Komisija podnosi predlog kojim se preciziraju modaliteti prijave iz člana 158(1) Pravila primene u skladu sa kojim odbor za procenu treba da proceni i rangira ponude isključivo na osnovu kriterijuma za dodelu dok kriterijumi za isključenje i izbor treba da budu procenjeni drugim odgovarajućim sredstvima koja garantuju odsustvo

sukoba interesa. Predlog će biti podnet UOOPN-u na odobrenje u skladu sa članom 7.

2. Ponude se ocenjuju na nediskriminatorski način. Ne dovodeći u pitanje stav 1, procena se zasniva na kriterijumima za isključenje, izbor i dodelu navedenim u specifikacijama iz člana 16(2)(b) ili u zahtevima navedenim u bilo kom opisnom dokumentu za konkurentni dijalog.

3. Odbori za procenu vode pisano evidenciju o svojoj proceni u skladu sa članom 159(1) i (2) Pravila primene, koja će biti sastavljena zajedničkim dogovorom.

Ako se procena sprovode kroz dva odbora za procenu, kako je predviđeno u članu 8(2), pisani trag o proceni zasnovanoj na kriterijumima za isključenje i izbor može se sastaviti odvojeno od pisane beleške o proceni na osnovu kriterijuma za dodelu.

### **Poglavlje III**

#### **Zajedničke odredbe**

##### **Član 11**

###### **Organizacija sastanaka**

1. Komisija će sazvati sastanke UOSZN-a, UOOPN-a, odbora za otvaranje i odbora za procenu.

2. U meri u kojoj je to moguće i u slučaju hitnosti ili nepredviđenih okolnosti, sastanci UOSZN-a, UOOPN-a, odbora za otvaranje ili odbora za procenu se sazivaju najmanje četrnaest dana pre zakazanog datuma sastanka.

3. U meri u kojoj je to moguće i u slučaju hitnosti ili nepredviđenih okolnosti, i ne dovodeći u pitanje član 37, informacije ili dokumenti relevantni za sastanke iz stava 1 podnose se članovima UOSZN-a, uključujući i svakog posmatrača, UOOPN, odbor(e) za otvaranje ili odbore za procenu, najmanje četrnaest dana pre zakazanog datuma sastanka.

4. Sastanci iz stava 1 održavaju se ili na mestu koje je stavila na raspolaganje Komisija ili putem audio ili video-konferencije.

5. Komisija neće nadoknaditi troškove putovanja, smeštaja ili troškove dnevnicu licu koje je imenovala druga ugovorna strana koja učestvuje na sastanicima navedenim u stavu 1.

### **Glava III**

#### **POSTUPAK NABAVKE**

##### **Član 12**

###### **Uloga Komisije u postupku zajedničke nabavke**

1. Komisija će, prema zahtevima ovog Sporazuma, obezbiti sveukupnu pripremu i organizaciju postupka zajedničke nabavke i olakšati proces sporazumnog rešavanja sporova između ugovornih strana koja proisteknu iz ovog Sporazuma i sprovođenja postupka zajedničke nabavke.

2. Komisija deluje za svoj račun i u ime ugovornih strana, kako je predviđeno ovim Sporazumom.

3. Komisija je jedini predstavnik ugovornih strana u odnosu na privredne subjekte, kandidate ili ponuđače tokom postupka zajedničke nabavke, uključujući sva pitanja koja proisteknu u vezi sa postupkom zajedničke nabavke nakon dodele okvirnih ugovora.

4. Komisija će biti jedini predstavnik ugovornih strana u bilo kom sudskom postupku u skladu sa članom 4 stavovi 3 do 5 ovog Sporazuma.

5. Komisija može od jedne ili više ugovornih strana zatražiti pomoć u postupku odbrane ili tokom pokretanja bilo kog sudskog postupka. Zamoljene ugovorne strane će nastojati da pruže takvu pomoć i uzdržavaće se od bilo kakve radnje koja bi mogla ugroziti odbranu ili pokretanje bilo kog takvog sudskog postupka.

Ugovorna strana će pružiti pomoć Komisiji tamo gde je ta ugovorna strana imenovana u postupku.

6. Komisija pruža administrativnu podršku tokom postupka zajedničke nabavke i okvirnih ugovora. Ovo uključuje:

(a) sastavljanje potrebne dokumentacije i administrativne prepiske u ime ugovornih strana;

(b) vođenje evidencije o sastancima UOSZN-a, UOOPN-a, odbora za otvaranje i procenu;

(v) postizanje odgovarajućih dogovora za postupanje sa informacijama ili dokumentima vezanim za postupak zajedničke nabavke ili okvirne ugovore.

### **Član 13**

#### **Početak postupka nabavke**

1. Svaki član UOSZN-a može predložiti pokretanje postupka nabavke. Ovim predlogom će biti identifikovana medicinska sredstva koja je potrebno nabaviti. Postupak nabavke će se pokrenuti ukoliko najmanje pet ugovornih strana, uključujući Komisiju, glasa za pokretanje takvog postupka i obavesti o ovoj nameri predsedavajućeg UOSZN-a.

2. Komisija, nakon konsultacija sa ostalim ugovornim stranama koje žele da pokrenu postupak nabavke, izdaje razuman rok u kom ostale ugovorne strane mogu izraziti interesovanje za učešće u postupku nabavke.

3. Svaka od ugovornih strana koja je izrazila interesovanje za učešće u postupku zajedničke nabavke detaljno opisuje svoje potrebe za nabavkom Komisiji u vremenskom okviru koji je Komisija utvrdila nakon odobrenja UOOPN-a, u skladu sa članom 7.

### **Član 14**

#### **Vrsta postupka nabavke**

1. Nakon pokretanja postupka nabavke u skladu sa članom 13, UOOPN odlučuje, u skladu sa članom 7, o vrsti postupka nabavke koji treba da se usvoji, u odnosu na navedene u članu 104(1)(a) do (e) Finansijske uredbe na osnovu načela utvrđenih u članu 102 te uredbe i članova 127 i 137 Pravila primene.

2. Vrsta postupka nabavke biće navedena u pozivu za podnošenje ponuda iz člana 103 Finansijske uredbe i člana 123(3) Pravila primene.

### **Član 15**

#### **Vrsta i trajanje ugovora**

1. Nakon pokretanja postupka nabavke u skladu sa članom 13, UOOPN će u skladu sa članom 7 odobriti:

(a) vrstu ugovora koji će biti dodeljen na osnovu načela utvrđenih u članu 101 Finansijske uredbe i u članovima 121 i 122 Pravila primene;

(b) trajanje okvirnog ugovora kao i modaliteta za njegovu reviziju u skladu s prvim podstavom člana 122(1) i člana 122(4) Pravila primene.

2. Vrsta ugovora i njegovo trajanje određuju se u pozivu za podnošenje ponuda.

### Član 16

#### **Sadržaj konkursne dokumentacije**

1. Sadržaj celokupne konkursne dokumentacije koja se odnosi na postupak javne nabavke započet u skladu s članom 13, utvrđuje Komisija u skladu sa odgovarajućim odredbama Finansijske uredbe i Pravila primene, uz poštovanje mišljenja UOOPN-a, u skladu sa članom 7.

2. Bez obzira na prvi stav:

- (a) poziv za podnošenje ponuda, uključujući opis partije, ukoliko ga ima;
- (b) tehnička specifikacija i kriterijumi za isključenje, izbor i dodelu;
- (v) bilo koji opisni dokument, u slučaju postupka konkurentnog dijaloga;
- (g) nacrt ugovora;
- (d) pozivno pismo za podnošenje ponuda kojim se postavljaju zahtevi za podnošenje;

usvaja se nakon odobrenja UOOPN-a, u skladu sa članom 7.

### Član 17

#### **Kriterijumi raspodele**

1. Učestalost dodeljivanja raspoloživih količina medicinskih sredstava između ugovornih strana koje učestvuju („opšte primenljivi kriterijumi za dodelu“) dostavlja se UOOPN-u na odobrenje u skladu sa članom 7.

Ugovorne strane će dobiti ukupnu količinu medicinskih sredstava koju su rezervisali ili naručili, ali će brzina isporuke zavisiti od proizvodnog kapaciteta ugovarača i od opšte primenljivih kriterijuma za raspodelu.

2. Ugovorna strana može, na dobro utemeljenim i potkrepljenim osnovama, kao što su problemi u isporuci ili zbog hitnih potreba, zatražiti odstupanje od opšte primenljivih kriterijuma za raspodelu utvrđenih u stavu 1, na određeni vremenski period.

Odstupanje je dozvoljeno samo nakon odobrenja UOOPN-a zajedničkim dogovorom. Predsedavajući će obavestiti UOOPN o svim odobrenim odstupanjima od opšte primenljivih kriterijuma za raspodelu, uključujući vremenski period za koji su takva odstupanja odobrena.

3. Stav 2 ne sprečava dve ili više ugovornih strana da se dogovore, na bilateralnoj na osnovi, o privremenom odstupanju od opšte primenljivih kriterijuma za raspodelu dogovorenih u skladu sa stavom 1 za okvirni ugovor koji su sklopili, za iznose na koje imaju pravo po tim kriterijumima.

Te ugovorne strane će obavestiti UOOPN o svakom takvom sporazumu, kao i o dogovorenom trajanju privremenog odstupanja.

Uslovi privremenog odstupanja od opšte primenljivih kriterijuma za raspodelu biće dogovoreni između ugovarača i ugovornih strana koje su ga usaglasile.

Ako se medicinska sredstva odnose na lekove, ugovarači će obezbediti da se odobri stavljanje lekova na tržište u državama članicama ugovornih strana, u skladu sa

Direktivom 2001/83/EK Evropskog parlamenta i Saveta od 6. novembra 2001.<sup>6</sup> ili Uredbom (EZ) br. 726/2004 Evropskog parlamenta i Saveta od 31. marta 2004.<sup>7</sup>

### Član 18

#### **Objavljivanje poziva za podnošenje ponuda**

1. Nakon pripreme konkursne dokumentacije u skladu sa članom 16 i odobrenja od strane UOOPN, Komisija će objaviti poziv za podnošenje ponuda u Službenom listu Evropske unije.
2. Komisija će na zahtev staviti privrednim subjektima na raspolaganje konkursnu dokumentaciju iz stava 1.

### Član 19

#### **Posebne odredbe u vezi sa otvaranjem prijava za učešće ili ponuda**

1. Prijave za učešće i ponude otvara odbor za otvaranje sastavljen od lica koja predstavljaju Komisiju u skladu sa članom 111(4) Finansijske uredbe i člana 157 Pravila primene.
2. Svaka ugovorna strana može zatražiti od Komisije da dozvoli jednom predstavniku te strane da posmatra otvaranje prijava za učešće ili ponuda.
3. Posmatrač neće učestvovati niti u raspravama odbora za otvaranje niti iznositi bilo kakve stavove članovima tog odbora.
4. Komisija će članovima UOOPN-a staviti na raspolaganje pisani trag o otvaranju prijava za učešće ili ponuda iz četvrtog podstava Člana 157(3) Pravila primene.

### Član 20

#### **Eliminacija kandidata ili ponuđača**

1. Ne dovodeći u pitanje drugi podstav člana 158(3) Pravila primene, samo zahtevi za učešće ili ponude koje ispunjavaju uslove u skladu sa prvim podstavom člana 158(1) Pravila primene, a koji nisu isključeni na osnovu kriterijuma za isključenje i koji ispunjavaju kriterijume za izbor, smatraće se prihvatljivim za procenu prema kriterijumima za dodelu, kako je predviđeno trećim podstavom člana 158(3) Pravila primene.
2. U svrhu primene prvog stava, i u skladu sa članom 10(2), odbor za procenu ispituje da li svaki zahtev za učešće ili ponuda ispunjavaju kriterijume za isključenje i kriterijume za izbor. Kada, zbog očigledne administrativne greške kandidata ili ponuđača, kandidat ili ponuđač ne dostavi dokaz ili ne da izjavu, primenjuje se član 96(2) Finansijske uredbe.

Kada odbor za procenu zaključi da kandidat ili ponuđač ispunjava kriterijume za isključenje i/ili ne ispunjava kriterijume za izbor, Komisija dostavlja na saglasnost UOOPN predlog kojim se taj kandidat ili ponuđač isključuje ili proglašava neuspešnim, u skladu sa članom 7. Takva odluka sprečava tog kandidata ili ponuđača da učestvuje u bilo kojoj daljoj fazi postupka zajedničke nabavke.

Predlog Komisije treba da bude praćen priloženom pisanom evidencijom o proceni iz člana 10(3) i sadrži navedene razloge zbog kojih se predmetni kandidat ili ponuđač isključuje ili proglašava neuspešnim.

<sup>6</sup>Direktiva 2001/83 / EZ Evropskog parlamenta i Saveta od 6. novembra 2001. o kodeksu Evropske zajednice koji se odnosi na lekove za ljudsku upotrebu (SL L 311, 28.11.2001, Str. 67).

<sup>7</sup>Uredba (EZ) br. 726/2004 Evropskog parlamenta i Saveta od 31. marta 2004. kojom se utvrđuju postupci Evropske zajednice za odobrenje i nadzor lekova za ljudsku i veterinarsku upotrebu i uspostavlja Evropska agencija za lekove (SL L 136, 30.4.2004, str. 1).

3. Komisija će obavestiti svakog kandidata ili ponuđača koji je isključen ili proglašen neuspešnim, u skladu sa ovim članom, o razlozima svoje odluke.

Obaveštavanje se vrši u skladu sa tačkom (a) prvog podstava člana 161(3) i drugog podstava člana 161(3) Pravila primene. Takvo obaveštavanje će se izvršiti što je pre moguće, nakon mišljenja UOOPN.

### Član 21

#### **Dodela ugovora**

1. Odluku o dodeli donosi Komisija u svoje ime i u ime ugovornih strana koje učestvuju, u skladu sa članom 113(1) Finansijske uredbe i članovima 149 i 159(3) Pravila primene, nakon odobrenja UOOPN u skladu sa članom 7.

2. Predlog Komisije treba da bude praćen kopijom pisane evidencije o proceni iz člana 10(3), kao i, ako Komisija predlaže da se ne slede preporuke odbora za procenu, napomenom kojom se obrazlažu razlozi za to da se one ne slede.

3. O odluci o dodeli se istovremeno obaveštavaju svi uspešni i neuspešni ponuđači ili kandidati, u skladu s članom 161(3) Pravila primene.

### Član 22

#### **Posebne odredbe koje se odnose na potpisivanje ugovora i stupanje na snagu**

1. Nakon usvajanja odluke o dodeli, i ne dovodeći u pitanje član 114 Finansijske uredbe, ugovorne strane koje učestvuju potpisuju ugovor.

2. Ugovor sa izabranim ponuđačem odobrava UOOPN u skladu sa članom 7, pre nego što je potpisani, ako se suštinski razlikuje od nacrtu ugovora, odobrenog u skladu sa članom 16(2)(d).

U svrhu primene prvog podstava, smatra se da se ugovor sa izabranim ponuđačem ne razlikuje suštinski od nacrtu ugovora ako su razlike ograničene na umetanje podataka koji nedostaju u nacrtu ugovora.

3. Potpisivanje ugovora podleže pravilima mirovanja predviđenim članom 171 Pravila primene.

4. Ugovor ne stupa na snagu sve dok ga ne potpišu ugovarači ugovorne strane koje učestvuju, u skladu sa stavom 1.

5. U hitnim slučajevima, nakon što je doneta odluka o dodeli i ne dovodeći u pitanje član 114 Finansijske uredbe, UOOPN može da, u skladu sa članom 7, ovlasti Komisiju da potpiše okvirni ugovor u ime i za račun svih ugovornih strana koje učestvuju.

### Član 23

#### **Posebne odredbe koje se odnose na kontakte sa privrednim subjektima, kandidatima ili ponuđačima tokom postupka zajedničke nabavke**

1. Komisija je jedina kontakt tačka između ugovornih strana i privrednih subjekata, kandidata, ponuđača ili njihovih predstavnika, u vezi sa bilo kojim pitanjem koje se odnosi na postupak zajedničke nabavke.

Komisija usvaja i objavljuje procedure za komunikaciju sa privrednim subjektima ili njihovim predstavnicima na svojoj veb stranici pre pokretanja postupka zajedničke nabavke.

Nakon pokretanja postupka zajedničke nabavke, kontakt između privrednih subjekata, kandidata, ponuđača ili njihovih predstavnika i Komisije, kao i drugih ugovornih strana ili njihovih predstavnika, može se odvijati, samo izuzetno, pod uslovima utvrđenim u članu 160(2) i (3) Pravila primene.

2. Svaka ugovorna strana osigurava da će lica koja obavljaju poslove u vezi sa ovim sporazumom za tu ugovornu stranu, ukoliko im se obrati privredni subjekat, kandidat, ponuđač ili njihov predstavnik u vezi sa bilo kojim pitanjem koje se odnosi na postupak zajedničke nabavke nakon stupanja na snagu ovog sporazuma, izjaviti da je, u skladu sa članom 23(1) ovog sporazuma, Komisija jedina kontakt tačka sa privrednim subjektima, kandidatima, ponuđačima ili njihovim predstavnicima, i uputiti svako takvo lice na Komisiju. One će istovremeno obavestiti Komisiju o detaljima tog obraćanja i upućivanja.

3. Svaki kontakt sa privrednim subjektima, kandidatima, ponuđačima ili njihovim predstavnicima iz stavova 1 i 2, uključujući i bilo kakvu razmenu prepiske, će biti uredno zabeležen.

Komisija obaveštava UOOPN o takvim kontaktima.

4. Ugovorne strane zadržavaju pravo da komuniciraju sa privrednim subjektima, kandidatima, ponuđačima ili njihovim predstavnicima u vezi sa postupcima nabavke izvan ovog sporazuma, uključujući i u vezi sa postupcima koji se odnose na nabavku medicinskih sredstava koja su predmet postupka zajedničke nabavke, ali da pri tome ne pominju bilo koje pitanje vezano za taj određeni postupak zajedničke nabavke.

#### Član 24

##### **Odustajanje i otkazivanje**

1. Ugovorne strane koje su pokrenule postupak nabavke mogu, zbog dobro utemeljenih i opravdanih razloga, da kolektivno odustanu od postupka zajedničke nabavke pre dodele ugovora, ili da kolektivno otkažu postupak dodele pre potpisivanja ugovora, u skladu sa prvim stavom člana 114 Finansijske uredbe.

Takvu odluku donosi Komisija nakon što je odobri UOOPN, na predlog Komisije ili bilo koje druge ugovorne strane koja učestvuje. Izuzetno od člana 7, predlog se usvaja ako prosta većina članova UOOPN koji su prisutni ili zastupljeni glasa za kolektivno odustajanje ili kolektivno otkazivanje.

2. U svrhu primene člana 114 Finansijske uredbe, poziv za dostavljanje ponuda treba da obezbedi da ugovorne strane koje učestvuju mogu ili da odustanu od postupka zajedničke nabavke pre dodele ugovora ili da otkažu postupak dodele pre potpisivanja ugovora, bez toga da kandidati ili ponuđači imaju pravo da zahtevaju kompenzaciju.

3. Čak i ako je predlog odobren u skladu sa stavom 1, UOOPN može da odustane od postupka zajedničke nabavke samo pre dodele ugovora ili da otkaže postupak dodele pre potpisivanja ugovora.

Sa odlukom UOOPN iz prvog podstava kandidati ili ponuđači treba da budu upoznati što je pre moguće.

4. Ugovorna strana koja je pokrenula postupak zajedničke nabavke može, zbog dobro utemeljenih i opravdanih razloga, da samostalno odustane od tog postupka pre nego što je ugovor dodeljen, u skladu sa prvim stavom člana 114 Finansijske uredbe.

Ugovorna strana navodi razloge za svoju odluku o čemu se obaveštava UOOPN, kandidati ili ponuđači.

5. U svrhu primene člana 114 Finansijske uredbe, poziv za dostavljanje ponuda treba da obezbedi da ugovorna strana može da odustane od postupka zajedničke nabavke pre dodele ugovora, bez toga da kandidati ili ponuđači imaju pravo da zahtevaju kompenzaciju.

#### Član 25

### **Posebne odredbe koje se primenjuju u slučaju pregovaračkog postupka**

1. Ako se zajednička nabavka vrši putem pregovaračkog postupka, stavovi 2 do 8 se primenjuju na:

- (a) poziv za dostavljanje ponuda za pregovore;
- (b) pregovore sa ponuđačima ili njihovim predstavnicima;
- (v) ocenu ponuda.

2. U pregovaračkim postupcima bez prethodnog objavljivanja poziva za podnošenje ponuda u *Službenom listu Evropske unije*, Komisija dostavlja UOOPN na odobrenje nacrt užeg izbora kandidata koje predlaže da pozove na pregovore, u skladu sa članom 7.

3. Nakon odobrenja iz stava 2, Komisija u ime ugovornih strana koje učestvuju, poziva kandidate koji uđu u uži izbor na pregovore.

4. U pregovaračkim postupcima, nakon objavljivanja poziva za podnošenje ponuda u *Službenom listu Evropske unije*, postupak se može odvijati u fazama primenom kriterijuma za dodelu koji su utvrđeni u tenderskim specifikacijama, kako bi se smanjio broj ponuda o kojima će se pregovarati. Ako je to slučaj, u tenderskim specifikacijama treba predvideti da će se ova opcija koristiti i navesti na koji način će se koristiti.

Ako se koristi opcija predviđena prvim podstavom, odbor za procenu osnovan u skladu sa članovima 8 i 9 podnosi izveštaj o proceni, na odobrenje UOOPN u skladu sa članom 7, sa spiskom ponuđača koji će biti eliminisani iz učestvovanja u daljim fazama postupka zajedničke nabavke na osnovu primene kriterijuma za dodelu.

5. Nakon odobrenja navedenog u [drugom podstavu] stavu 4, Komisija, postupajući u ime ugovornih strana koje učestvuju, obaveštava svakog isključenog ponuđača o razlozima za njegovo isključenje iz daljih faza postupka zajedničke nabavke.

Obaveštavanje se vrši u skladu sa članom 161(3) Pravila primene. Ovo obaveštavanje će se izvršiti što je pre moguće nakon odobrenja UOOPN.

6. Pregovore vodi(e) odbor(i) za procenu osnovan(i) u skladu sa članovima 8 i 9 sa ponuđačima koji nisu isključeni ili proglašeni neuspešnim u skladu sa članom 20(2) ili primenom opcije predviđene stavom 4 ovog člana.

7. Pregovori će se odvijati u skladu sa članom 129 Pravila primene i na osnovu unapred objavljenih kriterijuma predviđenih u tenderskoj specifikaciji.

Ako se pregovori vode usmeno, odbor(i) za procenu iz stava 6 sačinjava(ju) pisani trag o pregovorima. On se šalje predmetnom ponuđaču, uz naznaku vremenskog roka za dostavljanje bilo kakvih predloženih izmena ili dopuna. Tokom sastanaka sa ponuđačima, odbor(e) za procenu treba da predstavljaju najmanje dva člana, od kojih je jednog odredila Komisija, a drugog imenovala država članica. Usmeni pregovori mogu se voditi samo ako postoji samo jedan kandidat, usled monopolске situacije, u skladu sa članom 134(1)(b) ili ako se pregovori odvijaju sa ponuđačem kojem je dodeljen početni ugovor, u situacijama iz člana 134(1)(e) ili (f) Pravila primene.

Ako u konkursnoj dokumentaciji nije drugačije određeno, pregovori su strogo ograničeni na sadržaj ponude i ne menjaju početne uslove tehničkih specifikacija i/ili ugovornih odredbi.

8. Tokom pregovora, odbor(i) za procenu može(gu) da zatraži(e) od ponuđača da izmene svoje ponude, i u tom slučaju se njihove ponude procenjuju na osnovu njihovih izmenjenih ponuda.

### **Posebne odredbe koje se primenjuju u slučaju konkurentnog dijaloga**

1. Ako se zajednička nabavka sprovodi putem postupka konkurentnog dijaloga, stavovi 2 do 7 primenjuju se na dijalog sa kandidatima i njihovim predstavnicima koji nisu isključeni ili proglašeni neuspšim u skladu sa članom 20 (2) ili primenom opcije predviđene u stavu 3. ovog člana.
2. Dijaloge vodi(e) odbor(i) za procenu osnovan(i) u skladu sa članovima 8 i 9, u saglasnosti sa članom 132 Pravila primene.

Odbor(i) za procenu vodi(e) zapisnik u pisanoj formi o dijalozima navedenim u prvom podstavu. On se upućuje dotičnom kandidatu, uz navođenje vremenskog roka za dostavu dopune ili ispravke. Odbor(i) za procenu takođe sastavlja(ju) izveštaj u kome se navodi opšta ocena o rezultatima dijaloga kao i preporuke, a naročito da li je potrebno zaključiti dijaloge.

Dijalozi se ne odnose na poziv za podnošenje ponuda ili narativa dokumenta na koji se poziva u članu 132 Pravila primene.

3. Dijalozi se mogu odvijati u uzastopnim fazama da bi se smanjio broj rešenja o kojima će se razgovarati primenom kriterijuma navedenih u narativu dokumenta koji prati poziv za podnošenje ponuda. Tamo gde je to slučaj, narativ dokumenta će odrediti da se ta opcija koristi i navesti kako će se koristiti.

Ako se koristi opcija predviđena prvim podstavom, odbor za procenu osnovan u skladu sa članovima 8 i 9 podnosi izveštaj o proceni, na odobrenje UOOPN u skladu sa članom 7, sa spiskom kandidata koji treba da budu isključeni iz učestvovanja u daljim fazama postupka zajedničke nabavke na osnovu primene kriterijuma navedenih u narativu dokumenta.

4. Po odobrenju navedenom u [drugom podstavu] stava 3, Komisija koja deluje u ime ugovornih strana o tome će obavestiti svakog kandidata koji je tako isključen o razlozima njihovog isključenja iz dalje faze postupka zajedničke nabavke.

Obaveštenje se vrši u skladu sa članom 161(3) Pravila primene. Takvo obaveštenje će se izvršiti što je pre moguće nakon odobrenja od UOOPN-a.

5. Pre zaključenja dijaloga, predlog kojim se kandidati obaveštavaju da su dijalozi zaključeni i pozivaju ih da podnesu svoje konačne ponude na osnovu rešenja predstavljenih i preciziranih tokom dijaloga, podnosi Komisija na odobrenje UOOPN-a u skladu sa članom 7.

6. Nakon odobrenja iz stava 5, Komisija koja deluje u ime dotičnih ugovornih strana, će obavestiti svakog učesnika u dijalužu da nije eliminisan prema stavu 4 zaključka dijaloga i pozvaće ih da dostave svoje konačne ponude na osnovu rešenja predstavljenih i preciziranih tokom dijaloga.

Obaveštenje se vrši u skladu sa članom 113(2) Finansijske uredbe i člana 161(3) Pravila primene. Takvo obaveštenje će biti napravljeno što je pre moguće po dobijanju odobrenja UOOPN-a.

7. Dostavljene ponude ocenjuje(u) odbor(i) za procenu pomenut(i) u stavu 2, u skladu sa drugim i trećim podstavom člana 132(4) Pravila primene.

### **Glava IV**

#### **DODELA I POTPISIVANJE POJEDINAČNIH UGOVORA ZASNOVANIH NA OKVIRNIM UGOVORIMA**

##### **Član 27**

**Dodela i potpisivanje pojedinačnih ugovora zasnovanih na okvirnim ugovorima**

1. Sprovođenje okvirnih ugovora vrši se kroz posebne ugovore zaključene između pojedinačnih ugovornih strana koje učestvuju i Sprorazuma o zajedničkim nabavkama ugovarača koji su strane ovih okvirnih ugovora.

Ugovorne strane na koje se odnosi okvirni ugovor mogu dodeliti i potpisati pojedinačne ugovore do maksimalnog broja medicinske opreme koje su rezervisali prema navedenom okvirnom ugovoru.

2. Svaka ugovorna strana dužna je da obavesti blagovremeno UOSZN o dodeli i zaključenju ugovora.

3. Sve ugovorne strane iz okvirnog ugovora potpisuju pojedinačne ugovore pre nego što okvirni ugovor istekne. Ti konkretni ugovori biće sprovedeni najkasnije 6 meseci nakon isteka odnosnog okvirnog ugovora. Odredbe odnosnog okvirnog ugovora će se i dalje primenjivati na pojedinačne ugovore po njegovom isteku.

4. Ugovorne strane kojima su dodeljeni i koji potpisuju pojedinačne ugovore biće u potpunosti odgovorne za sprovođenje ovih ugovora kao i za sledeće zadatke:

- a) obezbeđenje poštovanja uslova okvirnog ugovora prilikom primene pojedinačnih ugovora;
- b) obaveštavanje Komisije o kvalitetu i količini isporuke koja bi bila isporučena;
- v) prema potrebi, ocenjivanje ponuda za pojedinačne ugovore u slučaju ponovnog otvaranja nadmetanja;
- g) preuzimanje pojedinačnih budžetskih obaveza;
- d) izdavanje obrazaca naloga;
- đ) obezbeđivanje praćenja obrazaca naloga;
- e) ispunjavanje obaveze rokova plaćanja;
- ž) upravljanje ugovornim odnosima koji proizlaze iz pojedinačnih ugovora;
- z) poštovanje obaveze naknadnog objavljivanja dodele ugovora.

### Član 28

#### **Preusmeravanje rezervisanih količina**

Ugovorna strana može ponuditi rezervisanu količinu medicinske opreme pod okvirnim ugovorom u celosti ili delimično jednoj ili više ugovornih strana koje učestvuju u istom okvirnom ugovoru. Uslovi preraspodele rezervisanih količina se dogovoraju između ugovorne strane koja nudi i ugovorne strane koja ih prihvata.

### Član 29

#### **Preusmeravanje naloga**

1. Nakon dodele određenog ugovora u okviru okvirnog ugovora, ugovorna strana može ponuditi jednoj ili više ugovornih strana koja učestvuju u istom okvirnom ugovoru kupovinu u celosti ili deo naručene količine koja je još uvek preostala kod ugovarača. Uslovi preusmeravanja naručenih količina se dogovaraju između ugovarača, ugovorne strane koja nudi i ugovorne strane koja prihvata.

2. Ako su medicinska sredstva lekovi, ugovorna strana koja ih nabavlja će osigurati da ti lekovi budu u skladu sa Direktivom 2001/83/EZ<sup>6</sup> ili Uredbom (EZ) br. 726/2004<sup>7</sup>.

### Član 30

#### **Preprodaja isporuka**

1. Ugovorna strana može ponuditi jednoj ili više drugih ugovornih strana mogućnost kupovine medicinskih sredstava koja su već isporučena ugovornoj strani

koja nudi. Uslovi preprodaje dogovoraju se između ugovorne strane koja nudi i ugovorne strane koja kupuje i, ako je primenljivo, sa ugovaračem.

2. Ugovorna strana koja nudi i ugovorna strana koja kupuje će obezrediti da je takva preprodaja u skladu sa zakonom o javnim nabavkama i zakonom o konkurenciji i poštuje sve ugovorne odredbe po kojima ugovorna strana koja nudi može biti obavezana.

3. Ako su medicinska sredstva lekovi, ugovorna strana koja ih nabavlja će obezrediti da ti lekovi budu u skladu sa Direktivom 2001/83/EZ6 ili Uredbom (EZ) br. 726/2004<sup>7</sup>.

4. Mogućnost preprodaje medicinske opreme koja je već dostavljena ugovornoj strani jedne ili više država koja nije ugovorna strana podložna je sporazumu ugovorne strane koja nudi, države(a) koja(e) kupuje(u) i ugovarača. Ugovorna strana koja nudi i države(e) koja(e) kupuje(u) treba da obezbede da je takva preprodaja u skladu sa zakonom Unije o javnim nabavkama i zakonom o konkurenciji i poštuje bilo koje ugovorne odredbe na koje ugovorna strana koja nudi može biti obavezana.

### Član 31

#### **Donacija medicinske opreme**

1. Ugovorna strana može da donira medicinsku opremu stečenu u postupku zajedničke nabavke.

2. Pre donacije, ugovorna strana će o tome obavestiti UOSZN. Članovi UOSZN-a imaju sedam kalendarskih dana da izraze interesovanje za primanje donacije. Po isteku ovog perioda, ugovorna strana koja donira može odlučiti o korisniku donacija, uzimajući u obzir potrebe javnog zdravstva država koje zastupaju članice UOSZN-a, kao i drugih država i međunarodnih organizacija koje su izrazile interesovanje.

3. Ugovorna strana koja donira može tražiti povraćaj administrativnih troškova i troškova prevoza od države koja prima donaciju, a u vezi donacije.

### Glava V

## **ODREDBE KOJE SE PRIMENJUJU NA RUKOVANJE INFORMACIJAMA ILI DOKUMENTIMA**

### Član 32

#### **Deljenje informacija ili dokumenata**

Ugovorne strane će jedna drugoj dostaviti informacije ili dokumente za potrebe obavljanja njihovih uloga prema ovom Sporazumu.

### Član 33

#### **Profesionalna tajna**

1. Ne dovodeći u pitanje stav 2, osobama koje rade u vezi s ovim Sporazumom zabranjeno je, čak i nakon prestanka njihovih dužnosti, da objavljaju informacije obuhvaćene obavezom profesionalne tajne u smislu člana 339 Ugovora.

2. Ne dovodeći u pitanje član 35(2), informacije ili dokumenta na koje se odnosi obaveza profesionalne tajne kojom upravljaju ugovorne strane prema ovom Sporazumu se dele samo u skladu sa potrebama osoba koje rade u vezi sa ovim Sporazumom kako bi im se omogućilo da obavljaju funkciju ili zadatok povezan sa ovim Sporazumom. Pristup neće biti odobren samo zato što osoba zauzima određenu poziciju, čak ni ako je na višoj funkciji.

Jednom kada informacije ili dokumenti iz prvog podstava na zakonit način budu javno dostupni, obaveza profesionalne tajne se više neće primenjivati.

3. Svaka ugovorna strana mora da obezbedi da su sva lica koja rade za nju u vezi sa ovim Sporazumom zakonski obavezna da poštuju obaveze iz stavova 1 i 2 tokom njihovog zaposlenja i nakon prestanka njihovog radnog odnosa.

4. Ne dovodeći u pitanje član 38(1), kada lica koja rade u vezi sa ovim Sporazumom nisu zaposlena od ugovorne strane, ugovorna strana kojoj oni pomažu će sklopiti ugovorni odnos sa nadležnim poslodavcem koji onda nameće obaveze iz stavova 1 i 2 svojim zaposlenima.

#### Član 34

##### **Sukob interesa**

1. Svaka ugovorna strana mora da obezbedi da sva lica koja rade za nju u vezi sa ovim Sporazumom ne dođu u situaciju koja bi mogla da stvori sukob interesa ili na drugi način ugrozi nepristrasnost ili objektivnost svog rada u vezisa ovim Sporazumom tokom njihovog rada.

2. Ne dovodeći u pitanje član 38(1), kada lica koja rade u vezi sa ovim Sporazumom nisu zaposlene od strane ugovorne strane, ugovorna strana kojoj oni pomažu će sklopiti ugovorni odnos sa nadležnim poslodavcem koji nameće obaveze iz stava 1 svojim zaposlenima.

#### Član 35

##### **Upotreba informacija ili dokumenata**

1. Ugovorne strane neće koristiti nikakve informacije ili dokumente iz okvira ovog Sporazuma u druge svrhe osim onih koje se odnose na ovaj Sporazum.

2. U meri u kojoj je to moguće prema važećem zakonu Unije ili nacionalnom zakonu, bilo koja ugovorna strana koja razmatra objavljinjanje bilo kakvih informacija ili dokumenata koji su iz okvira ovog Sporazuma, će blagovremeno pisanim putem konsultovati autora podataka ili dokumenta pre objavljinjanja dotičnih informacija ili dokumenata i uzeće u obzir u najvećoj mogućoj meri stavove autora.

Ako prethodne konsultacije u skladu sa prvim podstavom nisu moguće, ugovorna strana će ipak obavestiti autora o objavljinjanju, uključujući i činjenične i pravne okolnosti koje se na njega odnose bez nepotrebnog odgađanja.

3. Svaka ugovorna strana mora da obezbedi da su sva lica koja rade za nju u vezi sa ovim Sporazumom zakonski obavezna da poštuju obaveze iz stavova 1 i 2 tokom njihovog zaposlenja i nakon prestanka njihovog radnog odnosa.

4. Ne dovodeći u pitanje član 37 stav 1, lica koja rade u vezi sa ovim Sporazumom a koje nije zaposlila ugovorna strana, ugovorna strana kojoj oni pomažu će sklopiti ugovorni odnos sa nadležnim poslodavcem koji nameće obaveze iz stavova 1 i 2 svojim zaposlenima.

#### Član 36

##### **Pristup dokumentima**

Ništa u ovom Sporazumu ne sprečava ugovornu stranu da poštuje odredbe prava Unije ili nacionalnog prava koje se na njega primenjuju u vezi s javnim pristupom dokumentima, zaštiti ličnih podataka ili zaštiti tajnih podataka.

#### Član 37

##### **Mere za zaštitu informacija ili dokumenata iz okvira ovog Sporazuma**

1. Komisija će predložiti posebna uputstva za rukovanje koja se primenjuju na informacije ili dokumente iz okvira ovog Sporazuma i mere zaštite koje se odnose na sastanke UOSZN-a, UOOPN-a i komisija za otvaranje ili ocenjivanje.

2. Uputstva za rukovanje koja se odnose na informacije ili dokumente kojima rukuje UOSZN i mere bezbednosti koje se primenjuju na sastanke UOSZN biće usvojene kao deo poslovnika ovog odbora na osnovu predloga Komisije.
3. Uputstva za rukovanje koja se odnose na informacije ili dokumente kojima rukuje UOOPN i mere bezbednosti koje se primenjuju na sastanke UOOPN biće usvojene kao deo poslovnika odbora na osnovu predloga Komisije.
4. Uputstva za rukovanje koja se odnose na informacije ili dokumente kojima rukuju odbori za otvaranje ili za procenu i mere bezbednosti koje se primenjuju na sastancima odbora za otvaranje ili procenu, uključujući bilo koji kodeks ponašanja za ocenjivače, će biti dostavljen UOSZN-u na odobrenje u skladu sa članom 7.
5. Svaki član odbora za procenu potpisuje Izjavu.

Predsedavajući odbora za procenu takođe može zahtevati od svakog člana odbora za procenu da potpiše kodeks ponašanja za ocenjivače iz stava 4.

### Član 38

#### **Poštovanje odredbi**

1. Svaka ugovorna strana će, prema svim drugim ugovornim stranama, imati odgovornost za poštovanje odredbi ove Glave, kao i nadoknađivanje svake štete prouzrokovane kršenjem ovih odredbi.
2. Svaka ugovorna strana preduzimaće odgovarajuće mere u skladu sa pravilima, zakonima ili propisima koji se na nju odnose kako bi:
  - (a) spričila otkrivanje informacija ili dokumenata koji su u okviru ovog Sporazuma, zaštićeni obavezom čuvanja profesionalne tajne, neovlašćenim licima;
  - (b) se pridržavala uputstava za rukovanje informacijama ili dokumentima koji su u okviru Sporazuma, pokriveni obavezom profesionalne tajne;
  - (v) spričila, otkrila i uklonila sukobe interesa koji mogu nastati pri izvršenju ovog Sporazuma.
3. Svaka ugovorna strana dužna je da bez odlaganja i odmah po otkrivanju kršenja odredaba ove Glave, gubitka ili neadekvatnog rukovanja informacijama ili dokumentima koji su zaštićeni ovom Glavom, preko svog predsedavajućeg o ovome obavesti Upravni odbor Sporazuma o zajedničkoj nabavci.

Predmetna ugovorna strana će u skladu sa pravilima, zakonima ili propisima koji se na nju primenjuju, odmah sprovesti istragu o kršenju, gubitku ili neadekvatnom rukovanju informacijama ili dokumentima, gde je poznato, ili postoje opravdane sumnje da su informacije ili dokumenta na koja se primenjuje obaveza profesionalne tajne, neadekvatno korišćene. Ugovorna strana će o rezultatima istrage izvestiti UOSZN.

Ne dovodeći u pitanje pravila, zakone ili propise koji se na njih odnose, ugovorne strane će sarađivati jedna s drugom u istrazi bilo kog kršenja odredaba ove Glave, neadekvatnog rukovanja ili gubitka informacija ili dokumenata zaštićenih ovim Glavom.

Ne dovodeći u pitanje peti podstav, ugovorne strane će sarađivati pri pronalaženju odgovarajućih rešenja za uklanjanje, saniranje ili ublažavanje uticaja bilo kakvog kršenja ove Glave.

Svaka ugovorna strana ostaće odgovorna za uklanjanje, saniranje ili ublažavanje uticaja bilo kakvog kršenja odredaba ove Glave čak i nakon konsultacija sa UOSZN.

## **ZAVRŠNE ODREDBE**

### Član 39

#### **Dužnost dosledne saradnje**

Ugovorne strane će preduzeti sve odgovarajuće mere, bilo opšte ili određene, kako bi se osiguralo ispunjenje obaveza ili bilo koje aktivnosti koje proističu iz ovog Sporazuma. Ugovorne strane će se uzdržati od bilo kojih mera koje mogu ugroziti ispunjenje ciljeva Odluke br. 1082/2013/EU i ovog Sporazuma.

Ovaj član ne dovodi u pitanje prava ugovornih strana da obavljaju postupke nabavki izvan ovog Sporazuma, čak ni kada ovi postupci podrazumevaju nabavku medicinskih sredstava koja su predmet zajedničke nabavke, okvirnog ugovora ili uključuju privredne subjekte ili ugovarače koji su, u tenderskoj proceduri, ili su potpisali okvirni ugovor u skladu sa postupkom zajedničke nabavke u okviru ovog Sporazuma.

### Član 40

#### **Posledice kršenja odredbi**

1. U slučaju da se bilo koja ugovorna strana ne pridržava ovog Sporazuma, ugovorne strane će uložiti napor da, u okviru UOSZN, brzo i zajednički odrede sredstva za rešavanje situacije u najkraćem mogućem roku.
2. U slučaju neslaganja dve ili više ugovornih strana u pogledu tumačenja ili primene ovog Sporazuma, te ugovorne strane će uložiti svoj najveći napor kako bi rešile problem direktno.

U slučaju da ovo nije moguće, bilo koja ugovorna strana koja je predmet neslaganja, može proslediti ovo pitanje UOSZN, gde će ugovorne strane uložiti svoj najveći napor u rešavanju ovog pitanja putem medijacije.

3. Ukoliko postupci navedeni u stavovima 1 i 2 ne otklone nepridržavanje ili ne reše neslaganje, u roku od tri meseca od prosleđivanja ovog pitanja UOSZN Sudu pravde u skladu sa članom 41.

### Član 41

#### **Nadležni sud za rešavanje sporova**

1. Svako nepoštovanje ovog Sporazuma ili neslaganje u pogledu tumačenja ili primene ovog Sporazuma između ugovornih strana koje ostane nerešeno unutar UOSZN, nakon primene člana 40(3), može biti doveden pred Sud pravde:
  - (a) Od strane predmetne(ih) ugovorne(ih) strane(a), u skladu sa članom 272 Ugovora ukoliko je tekući nerešeni problem između Komisije i jedne ili više država članica;
  - (b) Od strane predmetne(ih) ugovorne(nih) strane(a) koje su države članice, protiv bilo koje druge ugovorne(ih) strane(a) koja je (su) države članice, u skladu sa članom 273 Ugovora gde je tekući spor između dve ili više država članica.
2. Sud pravde će imati isključivu nadležnost da donosi odluke o bilo kakvom kršenju odredbi ovog Sporazuma u pogledu tumačenja ili primene ovog Sporazuma.
3. Sud pravde može doneti bilo koje rešenje koje smatra prikladnim za sve slučajevе dovedene pred njega u skladu sa ovim članom.

### Član 42

#### **Merodavno pravo i primena**

1. Pitanja ili sporovi koji proističu iz predmeta ovog Sporazuma biće regulisani primenljivim pravom Evropske Unije, odredbama ovog Sporazuma, i gde je to prikladno, zajedničkim opštim pravnim načelima država članica Unije.
2. Merodavno pravo za okvirne ili direktne ugovore ovog Sporazuma, i nadležni sud za razmatranje sporova po ovim ugovorima, biće određen ovim ugovorima.
3. Ukoliko jedna ili više odredaba ovog Sporazuma treba da, ili postane delimično ili u potpunosti nevažeća, nezakonita ili neprimenljiva u bilo kom pogledu prema važećem zakonu, validnost, zakonitost i primenljivost preostalih odredaba sadržanih u zakonu neće biti ugrožena.

#### Član 43

##### **Vanugovorna odgovornost i naknada za počinjenu štetu**

1. Ne dovodeći u pitanje članove 41 i 42, svaka ugovorna strana će u skladu sa pravom Unije, nadoknaditi svu vanugovornu štetu, nastalu iz primene ovog Sporazuma, trećim licima ili drugim ugovornim stranama, koju su prouzrokovali njeni organi ili bilo koje od drugih lica koja, u vezi sa ovim Sporazumom, rade za te organe.

Vanugovorna odgovornost Komisije koja proizlazi iz ovog Sporazuma, uređena je drugim stavom člana 340 Ugovora.

2. Ne dovodeći u pitanje članove 41 i 42, gde Komisija, u okviru svoje uloge predstavnika ugovornih strana, shodno članu 4, stavovima 3 do 5, mora da trećem licu ili ugovornoj strani nadoknadi vanugovornu štetu nastalu iz primene ovog Sporazuma, prouzrokovanoj, delom ili u celini, od strane jedne ili više ugovornih strana, u slučaju da strana(e) može(gu) biti identifikovana(e), predmetne ugovorna(e) strana(e) će obeštetiti Komisiju za celokupan iznos troškova koje Komisija nije prouzrokovala, uključujući i troškove bilo kakvog sudskog postupka.

3. Ne dovodeći u pitanje članove 41 i 42, gde Komisija, u okviru svoje uloge predstavnika ugovornih strana, shodno članu 4, stavovima 3 do 5, mora da trećem licu ili ugovornoj strani nadoknadi vanugovornu štetu nastalu iz primene ovog Sporazuma, prouzrokovanoj, delom ili u celini, od strane jedne ili više ugovornih strana, u slučaju da strana(e) ne može (gu) biti identifikovana(e), sve ugovorne strane će obeštetiti Komisiju za celokupan iznos troškova štete, uključujući i troškove bilo kakvog sudskog postupka.

Udeo štete koji nadoknađuje svaka predmetna ugovorna strana, uključujući udeo koji snosi Komisija, biće određen u skladu sa udelom svake strane u ukupnoj količini medicinskih sredstava koja su obuhvaćena određenim postupkom nabavke.

Ugovorna strana biće izuzeta iz obračuna nadoknade ukoliko može da dokaže da nije mogla čak ni delom da prouzrokuje nastalu štetu. Međutim, nijedna strana neće biti isključena iz obračuna samo na osnovu toga što nije bila deo UOSZN ili UOOPN koji je odobrio ili dao mišljenje u korist predloga koji je naneo štetu, nije bila prisutna ili imala zastupnika na sastanku, ili nije učestvovala u glasanju; takođe, ugovorna strana neće biti isključena iz obračuna ni na osnovu toga što se uzdržala pri glasanju ili glasala protiv predloga.

4. Ne dovodeći u pitanje članove 41 i 42, gde je Komisija pretrpela vanugovornu štetu nastalu iz primene ovog Sporazuma, prouzrokovanoj, delom ili u celini, od strane jedne ili više ugovornih strana, u slučaju da strana(e) ne može(gu) biti identifikovana(e), sve ugovorne strane osim Komisije će obeštetiti Komisiju za celokupan iznos troškova štete.

Udeo ukupne nadoknade prema Komisiji koji svaka predmetna ugovorna strana treba da plati biće izračunat u skladu sa drugim podstavom stava 3. Treći podstav stava 3 će biti primjenjen u skladu sa tim.

5. Ne dovodeći u pitanje članove 41 i 42, Komisija će za razliku od drugih ugovornih strana, biti jedina odgovorna za nadoknadu štete trećem licu ili drugoj(im) ugovornoj(im) strani(ama), koja je nastala iz primene ovog Sporazuma putem akta koje je Komisija usvojila bez odobrenja ili mišljenja Upravnih odbora u okviru ovog Sporazuma.

6. Ovaj član se ne primjenjuje na ugovornu odgovornost koja proističe iz ugovora.

#### Član 44

#### **Uslovi plaćanja i cene**

1. Ugovorne strane će se pridržavati svih cena i uslova plaćanja navedenih u:
  - (a) opisnom dokumentu koji prati poziv za podnošenje ponuda, u slučaju postupka konkurentskog dijaloga, u korist učesnika u dijalogu;
  - (b) okvirnom ugovoru sa ugovaračem nakon zaključenja.
2. Ugovorne strane odgovorne su za izmirenje bilo koje finansijske obaveze proistekle iz okvirnog ugovora direktno sa ugovaračem, srazmerno njihovom udelu u ukupnom broju medicinskih sredstava obuhvaćenih tim okvirnim ugovorom.

#### Član 45

#### **Preamble i prilozi**

Ovaj Sporazum će biti tumačen u skladu sa svojom preambulom i pravom Unije, posebno Odluke br. 1082/2013/EU, Finansijske uredbe i Pravila primene. Prilozi ovog Sporazuma čine njegov sastavni deo.

#### Član 46

#### **Amandmani**

Ugovorne strane mogu predložiti amandmane na ovaj Sporazum. Predloženi amandmani se predaju UOSZN u pisanoj formi, preko svog predsedavajućeg. Amandmani na Sporazum i njegovi prilozi se jednoglasno usvojaju od strane UOSZN. Amandman stupa na snagu i postaje sastavni deo ovog Sporazuma u skladu sa stavovima 4 i 5 člana 51.

#### Član 47

#### **Mandat i prestanak važenja**

1. Ovaj Sporazum će biti na snazi sve dok ne bude zamenjen drugim sporazumom u skladu sa stavom 2 ovog člana, ili ukinut u skladu sa stavom 3 ovog člana.
2. Na zahtev proste većine članova UOSZN, Komisija može predložiti da se ovaj Sporazum ukine ili bude zamenjen drugim. Predlog Komisije će po potrebi sadržati sveobuhvatni plan postepenog prelaska na alternativni okvir i nastavak garancija u međuvremenu.
3. Ovaj Sporazum će biti ukinut samo u slučaju jednoglasne odluke ugovornih strana u pisanoj formi.

#### Član 48

#### **Povlačenje ugovorne strane**

1. U slučaju da ugovorna strana odluči da se povuče iz Sporazuma, ugovorna strana će o ovome obavestiti UOSZN. Povlačenje iz Sporazuma neće imati

finansijske posledice po predmetne ugovorne strane pod uslovom da povlačenje stupa na snagu pre objavljivanja poziva za ponudu.

2. Ugovorna strana koja se povlači će nadoknaditi svaku štetu koja proističe iz njenih ugovornih obaveza na osnovu ugovora uređenih ovim Sporazumom.

#### Član 49

#### **Pristupanje drugih zemalja Sporazumu**

1. Ovaj Sporazum je otvoren za učešće bilo koje države članice Evropske unije, kao i države kandidate i člana Evropskog udruženja za slobodnu trgovinu, pod uslovom sklapanja međunarodnog sporazuma u ovu svrhu, prema članu 104(1),četvrti podstav, Finansijske uredbe.

2. Ukoliko zemlja među navedenima u stavu 1, odluči da pristupi Sporazumu, o tome će pisanim putem obavestiti UOSZN.

3. Potpisivanje Sporazuma od strane zemlje koja pristupa znači bezuslovno prihvatanje svih odredaba ovog Sporazuma, kao i svih odluka koje su Komisija i UOSZN već usvojili u vezi sa ovim Sporazumom od trenutka kada je Sporazum stupio na snagu, u skladu sa članom 51(4). Međutim, zemlja koja se pridružuje ne može učestvovati u postupcima nabavki koji su u toku.

#### Član 50

#### **Komunikacija**

Sva obaveštenja u skladu sa ovim Sporazumom su validna ako se daju u pisanim oblicima i dostave na adrese i kontakte načinima komunikacije predviđenim poslovnikom UOSZN-a.

#### Član 51

#### **Potpisivanje i stupanje na snagu**

1. Ovaj Sporazum se sačinjava i izvršava u jednakim verodostojnim jezičkim verzijama navedenim u Aneksu 4.

2. Ugovorne strane će potpisati jedan ili više primeraka svake jezičke verzije ovog Sporazuma. Potpisi na različitim primerima verodostojne jezičke verzije imaju isti efekat kao da su potpisani na jednom primerku ovog Sporazuma.

3. Komisija je depozitar svih potpisanih verodostojnih jezičkih primeraka ovog Sporazuma. Komisija će dostaviti propisno overene kopije ovog Sporazuma svakoj od ugovornih strana što je pre moguće nakon što primi potpisane primerke ovog Sporazuma od svih ugovornih strana.

4. Ovaj Sporazum stupa na snagu 14 dana od dana kada je: Komisija primila potpisane primerke ovog Sporazuma od svake ugovorne strane u svim verodostojnim jezičkim verzijama; Komisija potpisala svaki primerak u istim verodostojnim jezičkim verzijama; i da je jedna trećina svih ugovornih strana dostavila Komisiji potvrdu o završetku neophodnih nacionalnih procedura za stupanje na snagu ovog Sporazuma ili nepostojanje potrebe za takvim postupcima, kao što je priloženo u Aneksu 2.

5. Preostale dve trećine ugovornih strana biće obavezne da dostave potvrdu iz stava 4 u roku od 14 dana, od predaje te potvrde po ovom Sporazumu i svim aktima koje je UOSZN već usvojio u vezi sa ovim Sporazumom, od kada je ovaj Sporazum stupio na snagu, kako je utvrđeno u stavu 4.

#### Član 52

#### **Prelazne odredbe**

Ugovorne strane, osim Komisije, koje nisu obavestile Komisiju da je ovaj Sporazum stupio na snagu kod njih, kako je utvrđeno članom 51(4), mogu učestvovati u radu UOSZN-a kao posmatrači, podložno da takve države potpišu Sporazum o učešću u radu UOSZN-a kao posmatrači, kao što je priloženo u Aneksu 3.

Ugovorne strane, osim Komisije, koje nisu dostavile Komisiji potvrdu iz člana 51(4), neće se uzimati u obzir prilikom postizanja zajedničkog dogovora, kvalifikovane većine ili jednostavne većine u sklopu ovog Sporazuma.

### Član 53

#### **Objavljivanje**

Ovaj Sporazum i sve njegove izmene biće objavljene na svim zvaničnim jezicima onih ugovornih strana koje su države članice Unije u seriji „C“ Službenog lista Evropske unije.

RADI POTVRDE čega su dole potpisani, ovlašćeni, potpisali ovaj Sporazum.

## ANEKSI

### Aneks I

**Izjava o odsustvu sukoba interesa i zaštiti poverljivosti koju treba da daju članovi odbora za procenu, kako je navedeno u članu 37 (5)**

Naziv Sporazuma:

.....  
.....

Reference:

(Poziv za ponude br.):

.....  
.....

Ja, dole potpisani, .....  
postavljen [imenovan u odbor za procenu] [kome je data odgovornost za procenu kriterijuma za isključenje i odabir/ili kriterijuma za dodelu] za gore navedeni ugovor, izjavljujem da sam upoznat sa članom 57. Finansijske uredbe<sup>8</sup>, u kojem se navodi da:

*„1. Finansijski akteri i druga lica uključena u izvršenje i upravljanje budžetom, uključujući akte za pripremu, reviziju ili kontrolu, neće preduzimati nikakve radnje koje mogu dovesti u sukob njihove interese sa interesima Unije.*

*Ako postoji takav rizik, dotična osoba će se suzdržati od takve radnje i uputiće pitanje ovlašćenom službeniku delegacije koji pisanim putem potvrđuje da li postoji sukob interesa. Lice o kome je reč, takođe, će obavestiti svog nadređenog po hijerarhiji. Tamo gde postoji sukob interesa, dotična osoba prestaje sa svim aktivnostima u vezi s tim pitanjem. Službenik ovlašćen od strane delegacije će lično preuzeti sve dodatne odgovarajuće mere.*

*2. Za potrebe stava 1, sukob interesa postoji kada je nepristrasno i objektivno vršenje funkcija finansijskog aktera ili druga lica, kako je navedeno u stavu 1, ugroženo iz razloga koji uključuju porodični, emotivni život, politički ili nacionalni afinitet, ekonomski interes ili bilo koji drugi zajednički interes sa primaocem.*

*3. Komisija će biti ovlašćena da donosi delegirane akte u skladu sa članom 210 kojim se utvrđuje šta bi moglo predstavljati sukob interesa zajedno sa procedurom koja treba da se sledi u takvim slučajevima.”*

Izjavljujem da, koliko je meni poznato, nemam sukob interesa sa privrednim subjektima koji su se [prijavili za učešće] [dostavili ponudu] za ovaj ugovor, uključujući lica ili članove konzorcijuma, ili predložene podugovarače.

Potvrđujem da, ukoliko tokom evaluacije otkrijem da postoji takav sukob, odmah ću ga izjaviti i podneti ostavku iz odbora.

Takođe potvrđujem da ću sva pitanja koja mi budu poverena čuvati u tajnosti. Neću saopštiti izvan odbora nikakve poverljive informacije koje su mi otkrivene ili koje sam

---

<sup>8</sup> Uredba (EU, Euratom) br. 966/2012 Evropskog parlamenta i Saveta od 25. oktobra 2012. o finansijskim pravilima koja se primenjuju na opšti budžet Unije i poništavaju Uredbu Saveta (EZ, Euratom) br. 1605/2002 (OJ L 298, 26.10.2012, Str. 1).

otkrio niti bilo kakve informacije koje se odnose na stavove iznete tokom procene.  
Neću koristiti na negativan način informacije koje su mi date.

[Slažem se da će se pridržavati odredaba Kodeksa ponašanja Komisije namenjenih za ocenjivače, čiji sam primerak dobio.]

Potpisao/la: .....

**Aneks II**

**Potvrda o završetku nacionalnih procedura za odobrenje ovog Sporazuma ili  
odsustvu potrebe za takvim procedurama kao što se navodi u članu 51(4)**

**[Zaglavljje organa koji predstavlja ugovornu stranu za potrebe ovog  
Sporazuma]**

Evropska komisija

Generalni direktor

Generalni direktorat za zdravlje i zaštitu potrošača

[Adresa]

Faks: [xxx]

**Re: Potvrda o završetku nacionalnih procedura za odobravanje Sporazuma o  
zajedničkim nabavkama za nabavku medicinskih protivmera ili odsustvu  
potrebe za takvim procedurama u skladu sa članom 51(4) tog Sporazuma**

Poštovani,

Pozivamo se na član 51(4) gore navedenog Sporazuma o zajedničkim nabavkama.

**ILI**

Obaveštavamo vas da su naše nacionalne procedure za odobravanje gore  
navedenog Sporazuma o zajedničkim nabavkama okončane na dan [datum].

**ILI**

Obaveštavamo vas da nisu potrebne nacionalne procedure za odobravanje gore  
navedenog Sporazuma o zajedničkim nabavkama od strane [ime ugovorne strane].

S poštovanjem,

[Ime ugovorne strane]

[Nadležna nacionalna institucija]

[Ime, funkcija]

[Adresa]

Faks: [xxx]

**Aneks III****Sporazum o učešću u radu Upravnog odbora Sporazuma o zajedničkim nabavkama u svojstvu posmatrača iz prvog stava člana 52****[Zaglavljje organa koji predstavlja ugovornu stranu za potrebe ovog Sporazuma]**

Evropska komisija

Generalni direktor

Generalni direktorat za zdravlje i zaštitu potrošača

[Adresa]

Faks: [xxx]

**Re: Sporazum o učešću u radu Upravnog odbora Sporazuma o zajedničkim nabavkama kao posmatrača u skladu sa prvim stavom člana 52 Sporazuma o zajedničkim nabavkama medicinskih sredstava**

Poštovani,

U vezi sa prvim stavom člana 52 gore navedenog Sporazuma o zajedničkim nabavkama zaključenog između Komisije i država članica Evropske unije.

Imajući u vidu da učešće [ime ugovorne strane] u radu Upravnog odbora Sporazuma o zajedničkim nabavkama do završetka nacionalnih prodecura za [državu članicu] za odobravanje gore navedenog Sporazuma podleže sledećem:

- saglasnost [ime ugovorne strane] da se obavezuje članovima 5 do 6, članom 23, članovima 32 do Greška! Referentni izvor nije pronađen. 08, članovima 39 do 43, članom 50 i drugim stavom člana 52 gore navedenog Sporazuma o zajedničkim nabavkama; i
- poštovanje [od strane ime ugovorne strane] pravila procedure Upravnog odbora Sporazuma o zajedničkim nabavkama, uključujući sve mere donesene po navedenim pravilima.

Saglasni smo da se u ime [ime ugovorne strane] tako obavezujemo i da smo s tim usaglašeni.

S poštovanjem,

[Ime ugovorne strane]

[Nadležna nacionalna institucija]

[Ime, funkcija]

[Adresa]

Faks: [xxx]

**Aneks IV****Spisak verodostojnih jezičkih verzija ovog Sporazuma iz člana 51(1)**

španski  
češki  
danski  
nemački  
grčki  
engleski  
francuski  
hrvatski  
italijanski  
litvanski  
mađarski  
holandski  
portugalski  
slovački  
slovenački

Sastavljeno u Luksemburgu, dvadesetog juna dve hiljade četrnaeste godine.

Za Komisiju

Za Kraljevinu Belgiju

Za Republiku Bugarsku

Za Češku Republiku

Za Kraljevinu Dansku

Za Saveznu Republiku Nemačku

Za Republiku Estoniju

Za Irsku

Za Republiku Grčku

Za Kraljevinu Španiju

Za Republiku Francusku

Za Republiku Hrvatsku

Za Republiku Italiju

Za Republiku Kipar

Za Republiku Letoniju

Za Republiku Litvaniju

Za Veliko vojvodstvo Luksemburg

Za Mađarsku

Za Republiku Maltu

Za Kraljevinu Holandiju

Za Republiku Austriju

Za Republiku Poljsku

Za Republiku Portugaliju

Za Rumuniju

Za Republiku Sloveniju

Za Slovačku Republiku

Za Republiku Finsku

Za Kraljevinu Švedsku

Za Ujedinjeno Kraljevstvo Velike Britanije i Severne Irske

Za Kraljevinu Norvešku

Za Island

Za Kneževinu Lihtenštajn

Za Crnu Goru

Za Republiku Severnu Makedoniju

Za Republiku Albaniju

Za Republiku Srbiju

Ministar finansija

Siniša Mali

Za Bosnu i Hercegovinu

Za Kosovo\*

\*Ovaj naziv je bez prejudiciranja statusa i u skladu je sa Rezolucijom Saveta bezbednosti Ujedinjenih nacija 1244 i mišljenjem Međunarodnog suda pravde o deklaraciji o nezavisnosti Kosova.



Brisel, 5.3.2015

C(2015) 1407 konačno

### **ISPRAVKA**

**Konačne Odluke Komisije C(2014)2258 od 10. aprila 2014. godine o  
odobrenju Sporazuma o zajedničkim nabavkama medicinskih sredstava u  
skladu sa Odlukom  
1082/2013/EU**

**U članu 7(3) Aneksa**

umesto: „Ako se predlog ne usvoji kvalifikovanom većinom prisutnih ili zastupljenih članova relevantnog Upravnog odbora, onda se, ne dovodeći u pitanje stav 5, organizuje drugo glasanje na narednom sastanku. Izuzetno od stava 3, predlog će se smatrati odobrenim od strane Upravnog odbora ako je izglasan prostom većinom prisutnih ili zastupljenih članova koji glasaju u ime ugovornih strana čije učešće u proceduri iznosi minimum 50% ukupnih stvarnih troškova (ili, ukoliko stvarni troškovi još nisu poznati, procenjenih troškova) medicinskih sredstava koje pokriva postupak zajedničke nabavke, ili, gde je primenjivo, pokrivaju Ugovorne strane u UOOPN.

Ako predlog ne može biti usvojen prostom većinom, onda će, ne dovodeći u pitanje stav 5, treće glasanje biti održano na narednom sastanku. Ako prosta većina, onako kako je definisana prvim podstavom, ponovo ne može da se postigne, predlog će se smatrati odobrenim osim ako postoji kvalifikovana većina protiv istog“.

čitati: „Ako se predlog ne usvoji kvalifikovanom većinom prisutnih ili zastupljenih članova relevantnog Upravnog odbora, onda se, ne dovodeći u pitanje stav 4, organizuje drugo glasanje na narednom sastanku. Izuzetno od stava 2, predlog će se smatrati odobrenim od strane Upravnog odbora ako je izglasan prostom većinom prisutnih ili zastupljenih članova koji glasaju u ime ugovornih strana čije učešće u proceduri iznosi minimum 50% ukupnih stvarnih troškova (ili, ukoliko stvarni troškovi još nisu poznati, procenjenih troškova) medicinskih sredstava koje pokriva postupak zajedničke nabavke, ili, gde je primenjivo, pokrivaju Ugovorne strane u UOOPN.

Ako predlog ne može biti usvojen prostom većinom, onda će, ne dovodeći u pitanje stav 4, treće glasanje biti održano na narednom sastanku. Ako prosta većina, onako kako je definisana prvim podstavom, ponovo ne može da se postigne, predlog će se smatrati odobrenim osim ako postoji kvalifikovana većina protiv istog“.

**U članu 7(4) Aneksa**

umesto: „Kada je potrebno hitno odobrenje predloga od strane Upravnog odbora, on će se održati telefonskim putem ili na drugi odgovarajući način komunikacije na daljinu, a uzastopna glasanja iz stava 3 mogu se održati na istoj sednici“.

čitati: „Kada je potrebno hitno odobrenje predloga od strane Upravnog odbora, on će se održati telefonskim putem ili na drugi odgovarajući način komunikacije na daljinu, a uzastopna glasanja iz stava 2 i 3 mogu se održati na istoj sednici“.

#### U članu 7(5) Aneksa

umesto: „Bez obzira na prvi podstav stava 1, stavovi 3 i 4 ne primenjuju se ako se ovim Sporazumom zahteva jednoglasan dogovor članova Upravnog odbora“.

čitati: „Bez obzira na prvi podstav stava 1, stavovi 2 i 3 ne primenjuju se ako se ovim Sporazumom zahteva jednoglasan dogovor članova Upravnog odbora“.

#### U članu 25(5), prvi podstav Aneksa

umesto: „Nakon odobrenja navedenog u [drugom podstavu] stavu 4, Komisija, postupajući u ime ugovornih strana koje učestvuju, obaveštava svakog isključenog ponuđača o razlozima za njegovo isključenje iz daljih faza postupka zajedničke nabavke“.

čitati: „Nakon odobrenja navedenog u drugom podstavu stava 4, Komisija, postupajući u ime ugovornih strana koje učestvuju, obaveštava svakog isključenog ponuđača o razlozima za njegovo isključenje iz daljih faza postupka zajedničke nabavke“.

#### U članu 26(4), prvi podstav Aneksa

umesto: „Nakon odobrenja navedenog u [drugom podstavu] stavu 3, Komisija, postupajući u ime ugovornih strana koje učestvuju, obaveštava svakog na taj način isključenog kandidata o razlozima za njegovo isključenje iz daljih faza postupka zajedničke nabavke“.

čitati: „Nakon odobrenja navedenog u drugom podstavu stava 3, Komisija, postupajući u ime ugovornih strana koje učestvuju, obaveštava svakog na taj način isključenog kandidata o razlozima za njegovo isključenje iz daljih faza postupka zajedničke nabavke“.

#### Aneksi, prva tačka Aneksa III

umesto: „[ime ugovorne strane] da se obavezuje članovima 5 do 6, članom 23, članovima 32 do Greška! Referentni izvor nije pronađen.8, članovima 39 do 43, članom 50 i drugim stavom člana 52 gore navedenog Sporazuma o zajedničkim nabavkama“.

čitati: „[ime ugovorne strane] da se obavezuje članovima 5 do 6, članom 23, članovima 32 do 38, članovima 39 do 43, članom 50 i drugim stavom člana 52 gore navedenog Sporazuma o zajedničkim nabavkama“.

**Član 3.**

Ovaj zakon stupa na snagu osmog dana od dana objavljivanja u „Službenom glasniku Republike Srbije – Međunarodni ugovori”.