

**PRINCIPLES AND PROCEDURES APPLICABLE TO PROCUREMENT CONTRACTS
AWARDED WITHIN THE FRAMEWORK OF HUMANITARIAN AID ACTIONS
FINANCED BY THE EUROPEAN UNION**

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1. Scope

- a) The Principles and Procedures applicable to Procurement Contracts awarded within the framework of Humanitarian Aid Actions financed by the European Union, as set out in Annex II of the Specific Grant Agreement (hereinafter referred to as 'Annex II'), contain mandatory principles, minimum standards and procedural requirements, which are to be applied by the Member State Specialized Agency (hereinafter referred to as the 'Agency') when procuring through property, supply, works or service contracts necessary for the implementation of Union-funded humanitarian aid actions. Annex II applies to all humanitarian actions, regardless of the value of the procurement contract, or the percentage of Union funding.
- b) The provisions and principles in Annex II are complementary to, and shall be read in conjunction with the General Conditions applicable to humanitarian actions financed by the Union set out in Annex I of the Specific Grant Agreement (hereinafter referred to as the 'General Conditions'). Pursuant to Article 3 of the General Conditions, the Agency shall ensure that its Implementing Partners also comply with Annex II when carrying out procurement activities.
- c) Where the Commission becomes aware, through an on-site audit or any other means, that the Agency's internal rules do not provide sufficient safeguards or procedures to ensure an adequate respect for the Mandatory Principles of humanitarian aid procurement pursuant to Article 3 herein, the Commission may make recommendations or it may request that the Agency complements or replaces the procedures already in place.
- d) The procedures applicable to Procurement Contracts, as set out in Annex II shall be carried out in accordance with the relevant Union legislation on public procurement. Pursuant to Article 9(2)(d) of the General Conditions, procurement procedures carried out in accordance with Union legislation on public procurement shall be deemed to have been done in accordance with the principles referred to in sections 3(2), 3(3), 3(4), 3(5), 3(6) and 3(8) of Annex II.

2. Definitions

For the purposes of Annex II, the following definitions shall be used:

- a) "Candidate" refers to an economic operator that has been invited by the Agency to submit an offer in a closed, negotiated or restricted procedure (i.e. any procedure that is not open to tender);
- b) "Contract" refers to an agreement concluded in writing and for monetary interests between an Agency and a contractor within the implementation of a humanitarian aid Action, financed in whole or in part from the Union's budget or from the European Development Fund;
- c) "Contractor" refers to any economic operator, being either a natural or a legal person, involved in the provision of supplies, works or services to the Agency by means of a contract. A buying agent or other profit-making entity specialised in offering technical assistance or procurement services to Agencies may also be considered as a contractor;
- d) "Property contract" covers contracts relating to immovable property, including land, buildings or other real estate;
- e) "Tenderer" refers to an economic operator that has submitted a tender to an Agency in the context of an open tender procedure;

f) "Urgent action" refers to a humanitarian aid Action addressing immediate and unforeseeable humanitarian requirements generated by sudden natural or man-made disasters, and it includes all actions financed under the European Commission's emergency financing decisions. An urgent action may also exist under other types of financing decisions where, for duly justified humanitarian reasons, the Parties agree that the implementation of the humanitarian Action has to start immediately.

3. Mandatory Principles of Humanitarian Aid Procurement

This Article reflects, and should be interpreted in the light of, the humanitarian aid principles of humanity, neutrality, impartiality and independence pursuant to Article 1(h) of the General Conditions.

3.1. Principle of Ethical Procurement

a) Agencies, tenderers, candidates and contractors must observe and uphold ethical standards in the procurement and execution of contracts. Minimum ethical standards include the avoidance of child labour¹, and the respect of basic social rights and working conditions based on international labour standards.

b) Where possible, the ethical standards shall also include environmental considerations and the avoidance by contractors of any connection with a party to a conflict, involvement in the supply or transport of illicit arms and/or land-mines, or involvement in the unethical exploitation of natural resources, in particular sensitive commodities such as precious metals, stones and rare earths.

c) The Agency may conduct on-site visits or use equivalent methods to ensure compliance of tenderers and contractors with this principle.

3.2. Principle of Sound Financial Management

The Agency shall ensure that contracts are awarded to the tenderer or candidate offering the best value for money, namely the tender or offer providing the best price-quality ratio available in the quantity and within the time frames required.

3.3. Principles of Equal Treatment, Non-Discrimination and Untied Aid

Without prejudice to the principle of supporting the local economy set out in Article 3(7) herein, the Agency shall ensure, within the applicable procurement procedure, that no discrimination or unjustified differentiation is made between legal or natural persons, regardless of the origin of the supplies or the nationality of the tenderer or candidate.

3.4. Principle of Transparency and Right of Access

a) The principle of transparency requires that all information linked to a procurement procedure is shared or published in an open and appropriate way to enable genuine competition, and to avoid any

¹ ILO defines child labour as work that deprives children of their childhood, their potential and their dignity, and that is harmful to physical and mental development. It refers to work that is mentally, physically, socially or morally dangerous and harmful to children, and interferes with their schooling, by depriving them of the opportunity to attend school, obliging them to leave school prematurely, or requiring them to attempt to combine school attendance with excessively long and heavy work (<http://www.ilo.org/ipec/facts/lang--en/index.htm>).

unfair treatment between candidates or tenderers with regard to access to information. Furthermore, the Agency's procurement decisions must be clearly justified and documented to enable a potential check that the procedures were conducted in keeping with the Mandatory Principles.

b) The right of access requires that the Agency grants the Commission or any organisation or person mandated by it, the European Anti-Fraud Office (OLAF) and the European Court of Auditors full and on-the-spot access to premises and documents, including procurement documents, decisions and supporting evidence, regardless of whether these belong to the Agency or any of its contractors. In this context, the Agency shall provide, upon request, complete information on the procurement procedures, documents, evaluations, award recommendations and contracts. The Agency shall abstain from any obstructive practice, which could hamper such right of access.

c) The Agency shall immediately inform the Commission in writing in the event of it becoming aware of any corrupt, fraudulent, collusive or coercive practice or established breach of the present rules, or of a situation likely to constitute a conflict of interest.

3.5. Principle of Proportionality

a) For the award of contracts whose estimated value exceeds EUR 60 000, the Agency shall have in place written procurement procedures that ensure proportionality between the procedures to be followed for awarding contracts and the value of those contracts. Closed, negotiated or restricted procurement procedures based on less than three candidates or tenderers should, in principle, be limited to reasonable amounts or be otherwise duly justified.

b) Procurement with an estimated value equal to or below EUR 60 000 shall, as a minimum, comply with the principles of ethical procurement, sound financial management, avoiding conflict of interest and, if applicable, shall comply with the provisions of Article 4 herein.

c) Where the subject-matter of a contract is sub-divided into several lots, the value of all lots together must be taken into account for the establishment of the procurement procedure to be used, even if each lot is subject to an individual contract. The estimated value of a contract may not be used to circumvent the principle of proportionality, nor may a procurement procedure be split up for that purpose.

d) Framework contracts shall not be used in such a way that their purpose or effect is to circumvent the principle of proportionality, or to prevent, restrict or distort fair competition.

e) The procurement procedure shall ensure the delivery of goods, works or services in the right quantity and of the right quality, within the required timeframe, and based on best value for money. The procurement procedures of the Agency shall include provisions on urgent actions and exceptional circumstances, while maintaining respect of the Mandatory Principles provided for in Article 3 herein.

f) When awarding contracts whose value exceeds EUR 60 000, in keeping with the principle of proportionality, the Agencies shall ensure that all procurement procedures are, as appropriate, open to the broadest degree of competition. This means that procurement procedures should, in principle, seek to engage at least three candidates or tenderers, provided that a sufficient number of candidates or tenderers exist and provided they satisfy the exclusion and selection criteria.

g) Within the framework of Union-funded humanitarian actions, the Agency may also apply, in addition to its internal procedures on exceptions, a procurement procedure based on a single offer in the following cases:

- (i) in urgent actions as defined in Article 2 herein;
- (ii) when procuring through a Humanitarian Procurement Centre (hereinafter referred to as 'HPC') in terms of Article 5 herein;
- (iii) for property contracts, whatever the estimated value of the contract, and after prospecting the local market. Pursuant to Article 8(4)(e) of the General Conditions, purchase of immovable assets may only be eligible by the Union in exceptional cases, when specified in the Specific Grant Agreement;
- (iv) after the initial procedure has been completed when no tenders or offers, or no suitable tenders or offers have been submitted in response to a competitive procurement procedure, provided that the original contract specifications are not substantially altered;
- (v) when, for technical or operational reasons, or for reasons connected with the protection of exclusive rights, the contract can only be awarded to a particular economic operator;
- (vi) for additional contracts consisting in the repetition or renewal of services, works or supplies entrusted to a contractor which was awarded with an earlier contract in the same region, provided that the terms of the original contract are not substantially altered. The period elapsed from the award of the first contract shall not be longer than one year. Contracts are not to be renewed on these grounds more than twice, except where duly justified and documented; and
- (vii) for additional supplies, works and services not included in the initial contract that, due to unforeseen circumstances, have become necessary for the performance of the Action, provided that the aggregate amount of additional supplies, works or services does not exceed 50% of the value of the initial contract.

3.6. Principle of Avoiding Conflicts of Interest

- a) The Agency shall take all necessary measures to prevent in the procurement procedures any conflict of interest as defined in Article 6 of the General Conditions, and shall ensure that members of any evaluation committee are aware of their duties of disclosure related to this principle.
- b) A contractor, providing technical assistance to the Agency in a procurement procedure, shall be precluded from submitting tenders or offers under that same procedure.

3.7. Principle of Supporting the Local Economy

Whenever possible and appropriate, the Agency shall endeavour to use local human or material resources, in order to help the economic recovery of populations affected by humanitarian crises. Before using local human or material resources, the Agency must ensure that this will not distort the local market, increase prices, or unduly burden either the local natural resources or the environment.

3.8. Principle of Due Diligence

- a) The Agency shall follow up on the timely delivery and satisfactory quality of the received supplies, works or services. Where delivery is late or where the quality or quantity falls below what was agreed with the contractor, the Agency shall take remedial measures, in order to mitigate any negative consequences for the beneficiaries and to ensure sound financial management.
- b) Where the Agency engages the services of a buying agent or other contractor to conduct procurement on its behalf, the Agency shall maintain full responsibility for the regularity of these procedures, and shall exercise due diligence to ensure full compliance with the rules and procedures established herein.

4. Special Provisions for the Procurement of Food and Medical Supplies

4.1. Scope and Definitions

- a) For the purposes of Article 4:

- (i) "Medical Supplies" shall include all medicines and other medical products, in particular those included on the national essential medical supplies list, national essential medicines list and on the World Health Organisation's (hereinafter referred to as the 'WHO') list of essential medicines², proprietary medicines or generics, medical devices and therapeutic food to address acute malnutrition. They shall not include veterinary products.

- (ii) "Food Supplies" shall include bulk consumable commodities, such as mixed foods, ready-to-use foods, fortified foods with added vitamins and minerals, and supplementary foods to address moderate malnutrition. They shall not include seeds for agricultural purposes.

- (iii) "Pre-Certified Supplier" and "Pre-Certification" refer to approved suppliers of medical supplies. A supplier is pre-certified where it has demonstrated, either to the Agency or to another entity described in Article 4(2)(d) herein, that its premises and facilities meet internationally recognised standards, for example by complying with Article 5(2) of the Guidelines on Good Distribution Practice of Medical Products for Human Use³, that it is technically capable of ensuring the quality of the active ingredients and that its products come from an approved supplier.

- (iv) "Pre-qualified Supplies" and "Pre-Qualification" refer to medical supplies. A medical supply is pre-qualified when it appears on the WHO's list of pre-qualified products, or when it has been approved by an entity described in Article 4(2)(d) herein, in keeping with the WHO's recommended norms.

- b) The provisions of Articles 4(2) and 4(6) herein shall be applicable in the procurement of food and medical supplies by all Agencies and shall have as their principal objective to ensure the quality of the products purchased. In order to achieve the quality required, these provisions are based on a

² The WHO Model List of Essential Medicines, which serves as a guide for the development of national and institutional essential medicine lists is updated and revised every two years by the WHO Expert Committee on Selection and Use of Medicines (http://www.who.int/selection_medicines/list/en/).

³ OJ C 68, 8.3.2013, p.1.

series of internationally recognised standards, which are, however, not exhaustive and may be updated. The Agency may also take as a quality reference any other equivalently recognised standards.

4.2. Medical Supplies

a) Irrespective of the value of the contract to be awarded, the Agency shall procure medical supplies either through an HPC in accordance with Article 5 herein, or by launching a procurement procedure with pre-certified candidates meeting the standards explained herein. Whenever feasible, the number of candidates invited shall be sufficient to ensure genuine competition.

b) When assessing offers submitted by pre-certified Candidates, the Agency shall compare prices and shall consult international medicines price databases, such as the International Drug Prices Indicator⁴, the Global Fund Price and Quality Reporting tool (PQR)⁵, the Price Information Exchange website (PIEMEDS)⁶, the global price reporting mechanism provided by the WHO AIDS Medicines and Diagnostics Service (AMDS)⁷ or MSF Untangling the Web of Antiretroviral Price Reductions⁸.

c) When comparing the costs of pharmaceutical products, the cost of the whole treatment per patient shall be taken into consideration, thus not only the cost per unit. Given that the procurement planning may also be influenced by other factors, such as transportation charges, storage requirements and shelf-life, the total cost necessary to uphold the required quality shall be considered.

d) When the Agency procures medical supplies itself, it shall only send the invitation to negotiate to pre-certified candidates which have demonstrated that their premises and facilities meet internationally recognised standards, e.g. as described in the Guidelines on Good Distribution Practice of Medical Products for Human Use, that they are technically capable of ensuring the quality of active ingredients and that their products come from approved suppliers. The invitation to negotiate shall at least include the following selection criteria to be used by the Agency when assessing the candidate(s):

(i) respect of the WHO's principles of Good Manufacturing Practice (hereinafter referred to as the 'GMP')⁹; where relevant, Good Storage Practices (hereinafter referred to as the 'GSP')¹⁰; Good Laboratory Practice (hereinafter referred to as the 'GLP'); Good Clinical Practice (hereinafter referred to as the 'GCP')¹¹, the WHO's model quality assurance standards

⁴ The International Drug Prices Indicator is regularly updated and provides a spectrum of prices from pharmaceutical suppliers and procurement agencies, based on their current catalogues or price lists. It also contains prices obtained from international development organisations and government agencies, and represents an essential tool to be used by Agencies to compare prices (<http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=english>).

⁵ <http://www.theglobalfund.org/en/procurement/pqr/>

⁶ Containing public sector procurement prices and suppliers for selected medicines that participating countries in the Western Pacific Region have shared voluntarily (<http://www.piemeds.com/>).

⁷ <http://www.who.int/hiv/amds/gprm/en/>

⁸ www.msfaccess.org

⁹ GMP (<http://apps.who.int/medicinedocs/documents/s18619en/s18619en.pdf>). These practices are most relevant where the Candidate is itself a manufacturer of medical supplies.

¹⁰ GSP (<http://apps.who.int/medicinedocs/documents/s18675en/s18675en.pdf>).

¹¹ GCP (http://apps.who.int/prequal/info_general/documents/GCP/gcp1.pdf).

MQAS¹², as well as the WHO's¹³ or the Union's Good Distribution Practices (hereinafter referred to as the 'GDP')¹⁴;

(ii) on-going monitoring of the production and quality control activities of both their supplies and suppliers, pursuant to the WHO publications referred to in this Article and an adequate quality control testing programme, including protocols and standard operating procedures, and based on a demonstrated risk analysis policy;

(iii) monitoring of customers' complaints and remedial follow-up, including recall procedures; and

(iv) any other recognition, which according to a recognised accreditation body, ensures compliance at least with one of the following standards or equivalent standards: United States QS (21 CFR part 820)¹⁵ on quality system regulation; ISO9001/2008¹⁶ on quality management system; ISO9002/1994 on quality assurance in production, installation and servicing.

e) When the Agency procures medical supplies itself, it shall be responsible for ensuring that they meet internationally recognised product standards. The procurement notice sent with the invitation to negotiate shall at least include the following award criteria to be used by the Agency when assessing the offer(s):

(i) respect of the minimum quality standards, such as the WHO's principles of GMP, GSP, GDP and GLP;

(ii) respect of the national drug regulations in the country of destination; and

(iii) respect of any intellectual property rights and patent regulation applicable in the country of operation.

f) Where the medical product already enjoys pre-qualification, or the supplier already benefits from pre-certification from an internationally recognised or reputable certification body that meets WHO recommended norms and standards for carrying out quality assessment, pre-qualification or pre-certification¹⁷, it shall be sufficient for the Agency to record documentation on this in its procurement file. Acceptable proof of quality in this respect may be issued either by the WHO, a Stringent Regulatory Authority¹⁸, or an HPC. If none of the previous proofs of quality are available in the country of operation, the proof of quality may be issued, after consultation of the Commission, by a

¹² MQAS (http://www.who.int/prequal/info_applicants/procagencies/prequal_procagencies.htm). These practices are most relevant where the Candidate is a wholesaler or intermediary and not itself a manufacturer of medical supplies.

¹³ GDP (<http://apps.who.int/medicinedocs/documents/s18678en/s18678en.pdf/>).

¹⁴ OJ C 68, 8.3.2013, p.1.

¹⁵ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1>

¹⁶ ISO 9001/2008 supersedes ISO9001/2000.

¹⁷ MQAS (http://www.who.int/prequal/info_applicants/procagencies/prequal_procagencies.htm).

¹⁸ The expression Stringent Regulatory Authority refers to a National Drug Regulatory Authority of a country participating either in the PIC/S (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme) and/or the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) initiatives.

National Drug Regulatory Authority, or an internationally recognised independent certification authority.

4.3. Medical Devices

a) "Medical device" refers to an instrument, apparatus, implement, machine contrivance, implant, in vitro reagent, or a component that provides a diagnosis, cure, mitigation, treatment, or prevention of a disease or condition, which does not achieve its intended use by being metabolized or through a chemical reaction. The Global Medical Device Nomenclature (GMDN) system designates 12 categories of medical devices, consisting of more than 10 000 generic groups. Medical devices include any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

- (i) intended by the manufacturer to be used, alone or in combination, for human beings; and
- (ii) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means, as defined by the Global Harmonization Task Force (hereinafter referred to as the 'GHTF')¹⁹.

b) The provisions of Articles 4(2)(a), 4(2)(b) and 4(2)(c) herein shall *mutatis mutandis* apply to the procurement of medical devices. The invitation to negotiate shall at least include the following contract specifications, to be used by the Agency in the award criteria when assessing the offer(s):

- (i) compliance with essential requirements as described by the GHTF²⁰;
- (ii) production in conformity with ISO standards and/or other equivalent standards as recognised by the GHTF;
- (iii) recognition by at least one of the regulatory authorities or an equivalent entity: MPALS License (Australia), Device License (Canada), CE Mark (EU), Device License (Japan), and 510 k Device Letter (USA); and
- (iv) priority shall be given to candidates that have been accredited by a recognised accreditation entity, thus providing proof of compliance with at least one of the following standards or equivalent: Japan QS Standard for medical devices 1128, ISO 13485²¹ on quality management system of an organization, and ISO9002/1994 on quality assurance in production, installation and servicing.

4.4. Veterinary medicines

The procurement of veterinary medicines, while not subject to the above-mentioned quality requirements, shall nonetheless be procured by the Agency with due respect of the applicable best

¹⁹ GHTF, SG1- N041R6 – essential principles of safety and performance medical devices (including *In Vitro* diagnostic devices) 2004. and GHTF SG1(PD) - N043R6 – labelling for medical devices (including *In Vitro* diagnostic devices) 2004 (http://www.hc-sc.gc.ca/dhp-mps/compliconform/int/part/ghtf_tc-tm_e.html).

²⁰ GHTF, SG1- N041R6 – essential principles of safety and performance medical devices (including *In Vitro* diagnostic devices) 2004. and GHTF SG1(PD) - N043R6 – labelling for medical devices (including *In Vitro* diagnostic devices) 2004 (http://www.hc-sc.gc.ca/dhp-mps/compliconform/int/part/ghtf_tc-tm_e.html).

²¹ ISO 13485 supersedes EN46001/ EN46002, ISO13485/ ISO13488.

veterinary practices in the field²² and, where possible, in consultation with an appropriately qualified animal health expert.

4.5. Destruction of Medical Supplies, Medical Devices and Veterinary Medicines

When procuring medical supplies, medical devices, or veterinary medicines, the Agency shall ensure that adequate provisions are in place to ensure respect of internationally recognised best practices in the destruction of any contract-related supplies that are recalled or expired.

4.6. Food supplies and transfers

a) When procuring food supplies, the Agency shall ensure that they:

- (i) comply with any quality standards laid down in the domestic legislation of the country of origin and/or the country of destination, whichever has the higher quality standard; and
- (ii) as much as possible, match the nutritional habits of the beneficiary population.

The costs of food supplies rejected due to failure to comply with the above-mentioned obligations shall not be eligible. Whenever possible and advisable, having due regard to the context in which the Action is implemented, and provided it does not substantially disturb the local beneficiary markets, priority shall be given to purchases in the country of operation or in neighbouring countries. The Agency shall obtain evidence based on local/regional market analysis that local/regional procurement would not induce market distortions which could adversely affect vulnerable populations.

b) The Agency shall be responsible for ensuring the quantity and quality of the supplies, including their packaging and marking:

- (i) when awarding urgent contracts or contracts with a value not exceeding EUR 300 000, the Agency may itself certify the quantity and quality of the supplies, by means of a suitably qualified member of staff;
- (ii) when awarding contracts of a value exceeding EUR 300 000, the Agency shall engage an independent recognised verification or inspection entity, namely a Monitoring Agency²³, which shall assume responsibility for verifying and certifying the quantity and quality of the supplies. Where a Monitoring Agency is used, the Agency shall include in the contractual documents the necessary provisions, so as to assure the right of access for the Commission pursuant to Article 3(4)(b) herein.

c) By derogation from Article 3(5) herein, when the object of the contract is the supply of fresh food, and, when the contract is divided into several lots taking into account the seasonal availability of products, each lot shall be considered individually in order to establish the applicable threshold.

d) Where applicable, the procurement notice shall specify the contractual Incoterms²⁴ delivery conditions applied to the supply contract, and shall identify the applicable Incoterm edition. When

²² <http://www.fve.org/news/publications/pdf/gvp.pdf>

²³ This includes any internationally recognised inspection company, preferably accredited to the standard norm ISO 45004 – ISO/IEC 17020 in the food production sector, contracted to verify and certify quantity, quality, packing and marking of food supplies.

²⁴ www.iccwbo.org/incoterms/id3042/index.html

the Incoterms specified in the procurement notice oblige the supplier to take out a transport insurance policy, this insurance shall cover at least the awarded tender amount and all risk associated with carriage.

e) Contracts concluded by the Agency shall include provisions on the accepted tolerance for weight and/or quantities delivered and they shall identify the procedure for establishing reductions of price for quality deviations and deliveries beyond the contracted delivery date or period.

5. Humanitarian Procurement Centres

a) An HPC is a non-profit organisation specialising in the procurement of supplies and services necessary for the delivery of humanitarian aid and the provision of related technical assistance, supply purchasing or logistics services. An HPC may either be an independent entity or a specialised supply or procurement department of a non-governmental organisation or an international organisation, provided that it has the appropriate levels of specialisation and discretion in procurement decisions.

b) The Commission's Directorate-General for Humanitarian Aid and Civil Protection – DG ECHO maintains a Register of suitably qualified HPCs, recognised in accordance with set procedures and criteria. The criteria for recognition as an HPC include, among others, appropriate legal personality and registration, non-profit nature, a non-discriminatory sales and fair pricing methodology and policy (including all overheads and mark-ups), expertise in procurement and related activities, well-documented and fair procurement procedures and quality assurance provisions, and an adequate financial and administrative capacity. HPCs play an important role in the global humanitarian aid effort, and as such conduct themselves with high levels of integrity, transparency and respect of Mandatory Principles of procurement set out in Article 3 herein. To verify compliance with above procedures, criteria and principles, the Commission performs periodic on-site examinations of recognised HPCs.

c) An Agency shall, when using the services of an HPC, apply the negotiated procedure with a single offer. In order to ensure an efficient procurement, the Agency should not request tenders or offers from several HPCs solely for price comparison purposes.

d) There is no contractual relation between the Commission and the HPC. The recognition by the Commission of an organisation as an HPC does not constitute an assurance with respect to the quality of individual products and services provided by the HPC or with respect to the HPC's compliance with contractual obligations towards third parties.

e) The Agency shall exercise the necessary degree of care, efficiency and diligence with regard to monitoring of the timeliness and quality of the supplies or services provided by an HPC. In cases where the quality or service falls below those expected and mentioned in Article 5(b) herein, the Agency shall inform the Commission of the shortcomings and circumstances.

6. Derogations from Annex II

a) Any necessary derogation from the obligations provided in Annex II shall be subject to prior and written approval from the Commission pursuant to Article 12(2) of the General Conditions. Any derogation shall be included in the Specific Grant Agreement.

b) Derogation from the obligations under Annex II may be founded on security, operational, technical or quality reasons, shortfall or unavailability of the supplies on the markets, costs or delays due to transport, legislation in the country of operation, or if the fulfilment of the contractual obligation would harm the Agency's mandate or the safety of its staff or beneficiaries.

c) While no derogation may be granted from the minimum quality assurances for medical supplies or food established in Article 4 herein, where the Agency, for circumstances beyond its control, is unable to demonstrate compliance with internationally accepted product standards, it may demonstrate instead that the supplies offer the best quality available. This includes at least compliance with the 'do-no-harm' principle and the standards accepted by the national or regional regulatory authorities. The Commission shall be informed of, and consulted on, these exceptional cases without unjustified delay.