

RULES AND PROCEDURES

APPLICABLE TO PROPERTY, SUPPLY, WORKS AND SERVICE CONTRACTS
AWARDED WITHIN THE FRAMEWORK OF HUMANITARIAN ACTIONS
FINANCED BY THE
EUROPEAN COMMUNITIES

Introduction

Annex IV of the European Community's framework partnership agreements with Humanitarian Organisations and with International Organisations¹ sets out mandatory standards and procedural requirements for the conduct of procurement by the Contracting Authorities when awarding property, supply, works and service contracts for the implementation of humanitarian Actions which receive the financial assistance of the European Community².

The nature and objectives of humanitarian aid, the context in which humanitarian Actions are implemented, including their rather short implementation period, and the need to guarantee in all cases the quality assurance of specific supplies, impose specific obligations on the Contracting Authorities while, on the other hand, justify flexible procedures and restricted market consultations.

Recognising these particular requirements, Article 238, paragraphs 2 and 3 of Commission Regulation laying down detailed rules for the implementation (hereafter the Implementing Rules)³ of the Council Regulation on the Financial Regulation applicable to the general budget of the European Communities (hereafter the Financial Regulation)⁴ mandates the European Commission to adopt specific provisions establishing the procedures to follow for awarding contracts in the framework of humanitarian Actions with a value of more than EUR 60,000.

Moreover, and in accordance with Article 184, paragraph 2, of the Implementing Rules, the rules and procedures of Annex IV are determined with due respect to the value of the contracts concerned, the relative size of the Community contribution in relation to the total cost of the Action and the management of risk.

With regard to risk management, the Directorate General for Humanitarian Aid (DG ECHO) has defined two types of control mechanisms to underpin risk management.

¹ The Directorate General for Humanitarian Aid of the European Commission, DG ECHO, has established specific procedures for the implementation and administration of humanitarian Actions financed by the European Community. These procedures are presented in the Framework Partnership Agreement with Humanitarian Organisations, the Framework Partnership Agreement with International Organisations and the implementing modalities of the Financial and Administrative Framework Agreement concluded between the European Community and the United Nations.

² And, where applicable, from the European Development Fund (EDF). All references to the funding of humanitarian Actions by the European Community in this text include the resources allocated from the EDF to the financing of humanitarian aid.

³ Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 (OJ L 357, 31.12.2002, p. 1), amended by Commission Regulation (EC, Euratom) No 1261/2005 of 20 July 2005 (OJ L 201, 2.08/2005, p. 3), Commission Regulation (EC, Euratom) No 1248/2006 of 07 August 2006 (OJ L 227, 19/8/2006, p. 3) and Commission Regulation (EC, Euratom) No 478/2007 of 23 April 2007 (OJ L 111, 28/4/2007). Hereafter refer to in the footnotes as IRFR.

⁴ Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 as amended by Council Regulation (EC, Euratom) N° 1995/2006 of 13 December 2006 (OJ L 390/2006 of 30 December 2006). Hereafter refer to in the footnotes as FR.

- One (called the P-control mechanism, "P" standing for *P*rior assessment and own Procedures) where DG ECHO assesses the technical capacity (internal control system, organisational procedures and financial solidity) and the procurement rules and procedures of the Contracting Authority prior to the signature of the Framework Partnership Agreement. The award of contracts will be ruled by the Contracting Authority's own procedures which have to be in line with the provisions of chapter 2 and 4 of Annex IV.
- The other (called the "A"-control mechanism, "A" standing for Action-related monitoring) where DG ECHO evaluates the management of procurement procedures and the technical capacity of the Contracting Authority during and after the implementation of the Action. Where the Action implemented by a Humanitarian Organisation is subject to an "A" control mechanism, the award of contracts for a value higher than EUR 60,000 will be ruled by the provisions of Annex IV. Equally, Annex IV in its entirety shall be applied by International Organisations for the award of contracts higher than EUR 60,000 when the European Commission has not established equivalence of the internal procurement rules of the International Organisation with the internationally accepted standards.

The Special Conditions of the individual Agreements signed with the Contracting Authority expressly identify the control mechanism to be applied.

The European Commission's Directorate General for Humanitarian Aid (DG ECHO) will publish 'Guidelines for the award of procurement contracts within the framework of Humanitarian Aid Actions financed by the European Community'⁵. Contracting Authorities implementing Actions subject to an "A" control mechanism are required to strictly conform to the procedures established in the Humanitarian Aid Guidelines for Procurement.

Annex IV identifies the Mandatory principles for all Contracting Authorities, regardless of the control mechanism applied to the individual Actions. Notably, Annex IV reiterates the obligation of transparency, proportionality, equal treatment and non-discrimination for all contracts financed in whole or in part by the budget of the Communities established in Article 89.1 of the Financial Regulation.

The principle ruling the participation in the award of procurement contracts adjudicated by Contracting Authorities for the implementation of a humanitarian Action financed in whole or in part by the European Community and the rules concerning the origin of the supplies set out in Annex IV have been drafted having due regard to the respect of the consuetudinary principles of International Humanitarian Law, in particular the principle of impartiality, meaning that the implementation of Actions must solely respond to identified needs, without discrimination of any kind and the principle of independence, which implies the autonomy of the humanitarian Action with regard to economic or other motivations. These principles are equally reflected in Council Regulation (EC) 1257/96 concerning humanitarian aid⁶ (hereafter Humanitarian Aid Regulation). Accordingly, humanitarian Actions have to be free from any tied aid interference. Furthermore, whenever feasible and advisable, Contracting Authorities shall endeavour to use local human and material resources as part of an integrated strategy to help the economic recovery of populations affected by humanitarian crises.

⁵ This publication is herein further referred to as " Humanitarian Aid Guidelines for Procurement"

⁶ Council Regulation (EC, Euratom) No 1257/96 of 20 June 1996 concerning humanitarian aid, OJ L 163, of 2 July 1996.

Annex IV sets out a number of Special Rules mandatory, when relevant, on all Contracting Authorities related to the implementation of humanitarian Actions:

- Pharmaceutical products and medical devices. In this respect it is necessary to underline the importance that the European Commission attaches to an effective quality assurance of pharmaceuticals and medical devices used or distributed by Contracting Authorities for the implementation of humanitarian Actions. To this end the key elements of the Guidelines for the Quality Assurance mechanisms for medicines and medical supplies⁷ published by DG ECHO have been incorporated in the text of Annex IV as Special Rules.
- Food Aid. Taking into account the specific requirements and constraints of the procurement of food aid in the framework of humanitarian Actions Special Rules have been drafted to regulate this matter.
- Humanitarian Procurement Centres. The experience gained in respect to the contribution of Humanitarian Procurement Centres to the efficiency and effectiveness of humanitarian Actions and its impact in the economy of the Actions, confirmed by audits, have been taken into account when drafting the Special Rules governing the cooperation between Humanitarian Procurement Centres and Contracting Authorities. The procedure for the assessment and control of Humanitarian Procurement Centres is detailed in the Humanitarian Aid Guidelines for Procurement.

Paragraphs of Annex IV are numbered in order to facilitate the identification of its provisions. Annex IV is divided into Chapters (one digit) and paragraphs (two or three digits). Paragraph may be divided in sub-paragraph identified by letters.

The structure of Annex IV of the Framework Partnership Agreement is the following:

Chapter 1 defines the key concepts used in the text.

Chapter 2 sets out the Mandatory Principles that govern the award of contracts in the framework of the implementation of humanitarian Actions, to be followed by all contracting Authorities regardless of the control mechanism applied to individual Actions.

Chapter 3 establishes the General Rules and Procedures to be followed by Contracting Authorities when awarding procurement contracts for the implementation of a humanitarian Action financed in whole or in part by the European Community. These provisions are applicable to procurement above EUR 60,000 for actions subject to the A-control mechanism and are further developed in detail in the Humanitarian Aid Guidelines for Procurement.

Chapter 4 defines the Special Rules applicable in cases of urgent Actions, for the purchase of medicaments and medical equipment, the procurement of food, the constitution of stocks, property contracts, Framework Contracts and Humanitarian Procurement Centres.

Chapter 5 sets out the Final Provisions.

⁷ http://ec.europa.eu/echo/pdf_files/evaluation/drugs_quality_guidelines.pdf

1. DEFINITIONS

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

- 1.1. The term **Contract** refers to an agreement for pecuniary interest concluded in writing by a Contracting Authority in the context of a humanitarian Action financed, in whole or in part, from a contribution from the Community budget (and where applicable, from the European Development Fund), in order to obtain, against a payment of a price the supply of products, the execution of works or the provision of services.
- 1.2. On the basis of their object, the following types of contracts can be established:
- (a) **Property** contracts cover the rental of land, existing buildings or other real estate. Purchase of immovable assets can never be financed by the Community contribution to an Action.
 - (b) **Supply** contracts cover the purchase, operational leasing⁸, rental or hire purchase, with or without option to buy, of products. The delivery of products may in addition include sitting, installation and maintenance.
 - (c) **Works** contracts cover either the execution, or both the execution and design, of works or the realisation, by whatever means, of a work corresponding to the requirements specified by the contracting authority. A 'work' means the outcome of building or civil engineering works taken as a whole that is sufficient by itself to fulfil an economic or technical function.
 - (d) **Service** contracts cover all intellectual and non-intellectual services other than those covered by supply contracts, works contracts and property contracts. Service contracts equally comprise study and technical assistance contracts.

A Study contract is a contract concluded which includes studies for the identification and preparation of projects, feasibility studies, technical studies and audits.

A Technical Assistance contract is a contract where the contractor is called on to play an advisory role, to manage or supervise a project or to provide the consultancy specified in the contract.

- (e) A contract covering both works and services shall be considered a service contract whenever the value of the services in question exceeds that of the works included in the contract. The same principle shall apply to define the procurement procedure to be followed in other **hybrid contracts**, i.e. contracts having as object a combination of different types of contracts.

⁸ For a complete definition of the concept of operational leasing please refer to www.ifac.org

- 1.3. The term **Humanitarian Organisation** refers to non-profit making autonomous organisations eligible for Community financing for the implementation of Actions under the Humanitarian Aid Regulation. It refers to National Societies of the Red Cross and Non-Governmental Organisations signatories of the Framework Partnership Agreement, hereafter FPA.
- 1.4. **Implementing Partner** refers to Humanitarian Organisations (both national and international), Specialised Agencies of the Member States, International Organisations and local authorities which are identified in the Action proposal as implementing partners. They assist the Contracting Authority in the implementation of the Action in the field. The relation between the Contracting Authority and its Implementing partners shall be based on the principle of not-for-profit and neither party may obtain financial benefits out of it.
- Implementing Partners for a Contribution or Grant Agreement⁹ (hereafter Agreements) holder are considered for the purposes of Annex IV as Contracting Authorities when the implementation of the tasks that they assume in the Action requires the award of Contracts.
- Local Contractors are not Implementing Partners.
- 1.5. The term **Contracting Authority** refers to those entities eligible for Community financing for the implementation of humanitarian Actions under the Humanitarian Aid Regulation and to which the rules and procedures of Annex IV apply.
- 1.6. **International Organisations**, in accordance with Article 43, paragraph 2, of the Implementing Rules, are international public sector organisations set up by intergovernmental agreements, specialised agencies set up by such organisations, the International Committee of the Red Cross and the International Federation of National Red Cross and Red Crescent Societies.
- 1.7. **Specialised Agencies** of the Member States are national public-sector bodies or bodies governed by private law but subject to special public supervision and governance rules with a humanitarian aid mission.
- 1.8. The expression **control mechanism** refers to the supervisory and monitoring procedure applied to each individual Agreement for identifying, assessing, and managing risks, carried out by the European Commission to provide reasonable assurance as regards the achievement of the objectives. The Special Conditions of the individual Agreements signed with the Contracting Authority expressly identify the control mechanism to be applied. Agreements may be subject to an:
- **"A" control mechanism** when the Contracting Authority shall apply for procurement procedures above EUR 60,000 the General Rules and Procedures established in Chapter 3 of Annex IV and in the Humanitarian Aid Guidelines for Procurement. Moreover, the Contracting Authority shall comply with the

⁹ The Directorate General for Humanitarian Aid concludes Grant Agreements with eligible Humanitarian Organisations and Contribution Agreements with International Organisations. In order to avoid reiterations in the text, both are referred to as Agreements.

Mandatory Principles established in Annex IV and apply, when relevant, the Special Rules.

- **"P" control mechanism** when the Contracting Authority will apply its own general procurement rules and procedures, while assuring in any case the compliance with the Mandatory Principles and applying, when relevant, the Special Rules.
- 1.9. The terms **supplier, works contractor and service provider** refer to economic operators, natural or legal persons, which offer to supply products, execute works and provide services respectively. The term Contractor is a general term used in this text to refer to all types of economic operators concluding contracts with the Contracting Authorities. Economic operators who have submitted a tender offer are referred to as Tenderers. Those who are invited to take part in a negotiated procedure are referred to as Candidates.
- 1.10. The **Contract Notice** is the publication by which the Contracting Authorities launch a procurement procedure. The Contract notice shall specify the rules governing the submission and presentation of tenders, the exclusion, selection and award criteria and set out the Technical Specifications or Terms of Reference.
- 1.11. **Award Notice** is the publication of the outcome of the award procedure and shall specify the type of product, service or works purchased, the amount of the contract and the successful candidate or tenderer.
- 1.12. **Technical Specifications** are tendering requirements for Supply and Works contracts that :
- set out the characteristics of supplies to be procured, such as quality, performance, safety and dimensions, or the process and methods for their production, or the processes or methods for their provision, including any applicable administrative provisions;
 - address terminology, symbols, packaging, marking or labelling requirements, as they apply to a supply or related services; or
 - set out conformity assessment procedures prescribed by a Contracting Authority.
- 1.13. **Terms of Reference** are requirements for a Service Contract which accurately define the characteristics of the service required with regard to the purpose for which it is intended and sets out conformity assessment procedures prescribed by a Contracting Authority.
- 1.14. A **Framework Contract**, sometimes also called long term agreement (LTA), is a contract concluded between a Contracting Authority and one or several economic operators for the purpose of laying down the essential terms governing a series of specific contracts to be awarded during a given period, in particular as regards the duration, subject, prices, conditions of performance and the quantities envisaged.
- 1.15. **Humanitarian Procurement Centres (HPCs)** are not for profit organisations specialised in the technical and commercial management of supplies and services necessary for the implementation of humanitarian Actions. They can provide

Technical Assistance in procurement to Contracting Authorities or supply pre-established stocks, purchasing or logistics capacity.

The Directorate General for Humanitarian Aid assesses those entities wishing to be recognised as Humanitarian Procurement Centres in accordance with the procedure established in the Humanitarian Aid Guidelines for Procurement. Only the recognition by the European Commission bears effects for the purposes of these rules. Use of HPCs to provide technical assistance or to supply pre-established stocks, purchasing or logistics capacity permits the Contracting Authorities to apply the negotiated procedure with a single tender under Annex IV.

Specialised supplies and procurement departments and services of international organisations can be also recognised as Humanitarian Procurement Centres.

- 1.16. **A Buying Agent** is a commercial structure specialised in the Technical Assistance to Humanitarian Organisations for the organisation of procurement procedures. The award of contracts for the performance of this service must be done in accordance with the applicable rules established in Annex IV. Use of Buying Agents to advise on, arrange or manage a procurement process does not remove from Contracting Authorities the requirement to comply with its obligations under Annex IV.
- 1.17. The term **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.

Examples of medical devices can include: walking stick, surgical instruments, contact lens lubricants, condoms, stethoscopes, insulin syringes and needles, wheelchairs, hearing aids, implantable devices, Magnetic Resonance Imaging (MRI), and Computed Tomography Imaging (CT). Therefore, medical devices include an enormous variety of existing healthcare items, and many new forms are being constantly invented. The Global Medical Device Nomenclature (GMDN) system designates 12 categories of medical devices consisting of more than 10,000 generic groups.

- 1.18. 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) initiatives¹⁰.
- 1.19. **Pre-qualification of potential candidates** is the process undertaken in defining a product or service needed, seeking expressions of interest from enterprises to supply the product or service, and examining the product or service offered against the

¹⁰ Currently **PIC/S**: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Malaysia, Netherlands, Norway, Portugal, Romania, Singapore, Slovak Republic, Spain, Sweden, Switzerland, United Kingdom. **ICH**: European Union Member States, Japan, and United States of America.

specification and the facility where the product or service is prepared against common standards of Good Manufacturing Practice (GMP)¹¹.

The examination of the product or service, and of the facility where it is manufactured, is performed by qualified inspectors against common standards. Once the product is approved, and the facility is approved for the delivery of the specified product or service, other Procurement Agencies are informed of the approval. Pre-qualification is required for all pharmaceutical products regardless of their composition and place of manufacture/registration, but the amount and type of information requested from the supplier for assessment by the Procurement Agency may differ.¹²

- 1.20. A **Monitoring Agency** is an internationally recognised inspection company or grouping of internationally recognised companies; 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.
- 1.21. **Urgent humanitarian Actions** are those intended to meet immediate and unforeseeable humanitarian requirements generated by sudden natural or man-made disasters.

Actions financed by European Commission's primary emergency and emergency decisions are always Urgent Actions.

The concept of Urgency also includes any situation financed under other types of financing decisions, duly justified, in which the implementation of the humanitarian Action has to start immediately and the delay incurred by putting out to tender procurement contracts would put lives at risk.

The concept of Urgency cannot be based on circumstances that can be attributed to the Contracting Authority.

2. MANDATORY PRINCIPLES

2.1. Scope of the Mandatory Principles

The provisions included in this Chapter shall govern the award of procurement contracts by all Contracting Authorities in the framework of the implementation of humanitarian Actions which receive the financial assistance of the European Community.

2.2. Ethical procurement

The European Commission requires that Contracting Authorities, Tenderers and Candidates observe the highest ethical standards during the procurement and execution of contracts.

¹¹ Link to GMP WHO: http://www.who.int/topics/pharmaceutical_products/en/

¹² Link to MQAS WHO: http://www.who.int/prequal/info_applicants/procagencies/prequal_procagencies.htm

The contracting authority shall satisfy itself with regard to the non-exploitation of child labour and the respect of basic social rights and working conditions by candidates and tenderers.

2.3. Principles governing the award of procurement contracts

Whenever the implementation of a Community financed or co-financed Action requires the Contracting Authority to award procurement contracts, the award procedure must comply with the principles of:

- Transparency in the procurement process;
- Proportionality between the procedures followed for awarding contracts and the value of the contracts;
- Equal treatment and non-discrimination of potential contractors and donors.

Contracts shall be awarded to the tender offering the best value for money¹³, that is to say, the best price-quality ratio, while taking care to avoid any conflict of interests¹⁴. The Contracting Authority shall take care of the timely delivery and satisfactory quality of the received supplies, works or services.

2.4. Organisational issues related to procurement procedures

Contracting Authorities shall establish standard written procedures on procurement and guidelines for tender documents. These standard procedures and guidelines shall comply with the Mandatory Principles enunciated in Chapter 2 and, as required, with the Special Rules set out in Chapter 4 herein. Standard procurement rules and procedures shall be equivalent to the General Rules and Procedures established in Chapter 3 and in the Humanitarian Aid Guidelines for Procurement.

Procurement procedures shall comply with the following rules:

- (a) All procurement contracts shall be put out to tender on the broadest possible base, having due regard to the requirements of the humanitarian Actions, the nature of the contract to be awarded and its value. This obligation is without prejudice to the specific procedures set out in the Special Rules herein.
- (b) Guidelines for tender documents must provide for the evaluation of proposals on the basis of exclusion, selection and award criteria announced in advance. The award criteria shall be weighted. The assessment of tender proposals shall be based on the necessary technical and administrative expertise. In accordance with the value of the contract, a committee may assess tenders.

¹³ Cf. Article 184.1 of IRFR

¹⁴ Cf. Article 52.2 of FR and 34.1 of IRFR

- (c) The procedures will ensure that all potential Contractors enjoy equal opportunity and equitable treatment on the basis of their financial, technical and commercial capacity.
- (d) The procedures will foresee that tenderers and candidates shall be excluded from participation in procurement procedures if they incur in one of the grounds set out in Article 93 of the Financial Regulation. Contracting Authorities shall establish the necessary verification procedure.
- (e) The procedures will avoid that contracts shall be awarded to tenderers or candidates who, during the procurement procedure for the contract in question find themselves in one of the situations referred to in Article 94 of the Financial Regulation.

2.5. Principles of eligibility of tenderers and candidates, origin of supplies

In accordance with the principles of impartiality and independence of Humanitarian Aid, participation in the award of procurement contracts shall be open to all legal or natural persons not falling under one of the causes of ineligibility or exclusion. The procurement procedure shall be free of any interference or conditionality due to tied aid such as origin of the supplies and nationality of the tenderers and candidates.

Contracting Authorities shall apply the principle of untying of aid and endeavour to use local human and material resources whenever it is possible and pertinent.

2.6. Regularity of tender procedures

Contracting Authorities shall reject any proposal put forward by tenderers or candidates, or, where applicable, terminate their contract, if it is determined that they have engaged in corrupt, fraudulent, collusive or coercive practices. To this end, contracting authorities are responsible to introduce the necessary provisions in the bidding and contractual documents.

- Corrupt practice is defined as is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the activities of the Contracting Authority;
- Fraudulent practice is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, the Contracting Authority to obtain a financial or other benefit or to avoid an obligation;
- Collusive practice is an undisclosed arrangement between two or more tenderers or candidates designed to artificially alter the results of the tender procedure to obtain a financial or other benefit;
- Coercive practice is impairing or harming, or threatening to impair or harm, directly or indirectly, any participant in the tender process to influence improperly its activities.

Contracting Authorities shall inform immediately the European Commission in writing in the event of being confronted by these practices, and provide all the relevant information. They shall also inform the European Commission under the

same terms about any suspected or established breach of the present rules as well as in case of any situation likely to constitute a conflict of interest. Finally, Contracting Authorities are invited to inform the European Commission in the event they become aware of other Contracting Authorities being confronted with such practices.

2.7. Tender documents

The Contracting Authority shall draft tender documents and guidelines in accordance with the best international practice. Tender Guidelines shall provide unequivocal Technical Specifications or Terms of Reference describing the object of the contract. When feasible, Technical Specifications have to be established in accordance with international recognised standards and contracts shall be established accordingly.

2.8. Contractual relations and due diligence of the Contracting Authority

The respective rights and obligations of the Contracting Authority and the contractors are governed by the tender documents and the contracts signed by the Contracting Authority and the latter. The Contracting Authority has the sole responsibility for complying with any contractual obligation incumbent on it.

The European Commission is not bound by contracts concluded by the Contracting Authority and recognises no contractual link between itself and the Contracting Authority's contractors.

The Contracting Authority shall verify the commercial information of any offer considered in a procurement procedure, including the authentication of the offer itself and, where relevant, the verification of the quantity, technical characteristics and quality.

Whenever the Contracting Authority requires the assistance of a Buying Agent or an Implementing Partner for the organisation of procurement procedures, it assumes the full responsibility for the regularity of the procedures in question and has to deploy due diligence to guarantee the compliance with the rules and procedures established herein.

Buying Agents or other service providers providing technical assistance to the Contracting Authorities in a procurement procedure shall be precluded from presenting tenders for contracts to be awarded under that same procedure.

Whenever a Humanitarian Procurement Centre provides Technical Assistance for launching and managing procurement procedures, the Contracting Authority shall assure itself that there are no situations of conflict of interest.

2.9. Transparency

Without prejudice to the specific requirements established in Chapter 4 hereafter, publication and advertising of contract notices must be sufficient and appropriate to ensure genuine competition and impartiality of the procurement procedure.

Advertising in specialised sites in the Internet, in the Contracting Authorities' Website and, when feasible, in technical magazines and trade publications may not

introduce any discrimination between candidates or tenderers nor contain details other than those contained in the Contract Notice.

Care should be taken to ensure adequate advance publication and reasonable time for the presentation of tenders. The time limits for the receipt of tenders and requests to participate, laid down in calendar days by the Contracting Authorities, shall be long enough to allow interested parties a reasonable and appropriate period to prepare and submit their tenders, taking particular account of the complexity of the contract.

If the humanitarian organisation wishes to refer to the European Community in the tender documents, the following clause should be included:

“(Name of the Contracting Authority) has received a grant from the European Community (or in appropriate cases, has presented a funding request to the European Community) for the implementation of the humanitarian Action entitled (name of the Action) and intends to apply a portion of that grant to payments under this contract. No party other than (Contracting Authority) shall derive any rights from the grant or have any claim to its proceeds. Under no circumstances or for no reason whatsoever will the European Community entertain any request for indemnity or payment directly submitted by the (Contracting Authority)'s contractors.”

2.10. Right of access and controls

The European Commission, or persons mandated by the European Commission, including the European Anti-Fraud Office (OLAF), and the Court of Auditors shall exercise their powers of control in accordance with the applicable regulatory provisions, on documents and on the spot, over all Contracting Authorities and contractors who have received Community funds. To this end, Contracting Authorities are required to include the necessary provisions in the bidding and contractual documents.

The Contracting Authority shall provide complete information on the procurement procedures, documents, bid evaluations, award recommendations and contracts to allow the Institutions and Services mentioned in the previous sub-paragraph to ensure that the procurement process is, or was, carried out in accordance with the applicable procedures.

Contracting Authorities shall abstain from any obstructive practice which could hamper the access or the exercise of the control.

3. GENERAL RULES AND PROCUREMENT PROCEDURES

3.1. Scope of the General Rules and Procedures

The provisions included in this Chapter shall govern the award of procurement contracts by Contracting Authorities for Agreements of more than EUR 60,000 with an A-control mechanism, in line with Article 184.2 of the Implementing Rules.

The provisions of this chapter must be applied in conjunction with the "Humanitarian Aid Guidelines for Procurement".

3.2. International publication

When the present rules prescribe international publication, the contracting authority shall advertise the contract notice in a specialised site in the Internet or subsidiarily in the Contracting Authority's Website and simultaneously in a periodical published at least in the country of operation, or if this is not possible by any other relevant means available.

The time limit for receipt of tenders shall be no less than 30 calendar days from the date on which the contract notice is published.

3.3. Local publication

When the present rules prescribe local publication, the contracting authority shall advertise the contract notice in a periodical published in the country of operation or, if this is not possible, by any other relevant means available.

The time limit for receipt of tenders shall be not less than 21 calendar days from the date on which the contract notice is published.

3.4. Estimation of the value of the contract

The estimated value of a contract may not be determined with a view to evading the requirements laid down in this Chapter, nor may a procurement procedure be split up for that purpose.

Where the subject of a contract is subdivided into several lots, even if each one will be subject of an individual contract, the value of all lots together must be taken into account for the overall evaluation of the applicable threshold.

3.5. Procurement procedures

Without prejudice to the specific procedures set out in Chapter 4 herein, procurement procedures shall take one of the following forms:

(a) Open procedure

Tender procedures are open whenever all interested economic operators may submit a tender after publication of a Contract notice. Contracting Authorities shall inform Tenderers of the outcome of the procedure by means of an Award Notice.

(b) Negotiated procedure

The negotiated procedure requires the Contracting Authorities to invite simultaneously and in writing the Candidates of their choice to negotiate the terms of the contract. The written communication shall be the means by which the Contracting Authorities make known their intention to launch procurement procedures and shall contain the same information as a Contract Notice. The number of Candidates invited to negotiate shall not be less than three, provided that a sufficient number of Candidates satisfy the selection criteria. In any event, the number of Candidates invited shall be sufficient to ensure genuine competition.

(c) Negotiated procedure with a single tender

Without prejudice to the provisions in 4.2, 4.6 and 4.7, Contracting Authorities may resort to a negotiated procedure with only one Candidate in the following cases:

1. Whenever no tenders/offers or no suitable tenders/offers have been submitted in response to an open or negotiated procedure after the initial procedure has been completed, provided that the original terms of the contract are not substantially altered;
2. Whenever, 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;
3. For additional Contracts consisting in the repetition/renewal of services, works or supplies entrusted to a Contractor awarded 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 can be renewed on these grounds for a maximum of two times;
4. For additional supplies, works and services not included in the initial Contract which, 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;
5. For Property Contracts, whatever the estimated value of the Contract and after prospecting the local market;
6. Contracts in respect of purchases on particularly advantageous terms, either from a supplier who is definitely winding up its business activities, or from the receivers or liquidators of a bankruptcy, an arrangement with creditors, or a similar procedure.

3.6. Thresholds and procedures for the awarding of contracts

When awarding contracts with a value of more than EUR 60,000, Contracting Authorities shall apply the following procurement procedures:

	Supply Contracts and Service Contracts	Works Contracts
Open Tender with International Publication	Estimated value of the Contract is EUR 300,000 or more	Estimated value of the Contract is EUR 3,000,000 or more
Open Tender with Local Publication	Estimated value of the Contract is EUR 150,000 or more but less than EUR 300,000	Estimated value of Contract is EUR 300,000 or more but less than EUR 3,000,000
Negotiated procedure	Estimated value of the Contract is less than EUR 150,000	Estimated value of Contract is less than EUR 300,000

Should the internal procurement rules of the Contracting Authority provide for more stringent procurement procedures or lower thresholds, the Contracting Authority may follow the procurement procedure established in its internal rules.

Detailed information on the procedure followed will be provided to the European Commission in the Final Reports or upon request.

4. SPECIAL RULES

4.1. Scope of the Special Rules

The Special Rules prescribe the specific procedures to be applied by all Contracting Authorities in the framework of the implementation of Urgent Actions and for the purchase of medical products and food. They set up the provisions ruling the constitution of stocks, the use of Framework Agreements and the relations with Humanitarian Procurement Centres.

4.2. Urgent Actions

In the framework of Urgent Actions, Contracting Authorities may place their orders, whatever the estimated value of the Contract, on the basis of a negotiated procedure with single tender.

4.3. Specific requirements for the procurement of pharmaceutical products¹⁵ and medical devices

- a) Contracting Authorities shall abide by international norms for the procurement of pharmaceutical products and shall respect patents and national drug regulations in the individual countries.
- b) The procurement of pharmaceutical products and medical devices shall have as principal objective to ensure the quality of the products purchased. To achieve this end, it shall be based at least on the pre-certification of potential candidates.
- c) The purchase of medicines shall be based on a pre-qualification scheme implemented either by the World Health Organisation, (WHO); or a Stringent Regulatory authority; or a UN organisation; or a Non-Governmental Organisation, a Humanitarian Procurement Centre or a specialized commercial operator which meet WHO recommended norms and standards for carrying out pre-qualification¹⁶.

Pre-qualification procedures should be based on the following principles:

- reliance on the information supplied by the relevant National Drug Regulatory Authority;

¹⁵ Veterinary products are not included under the scope of this Article.

¹⁶ MQAS http://www.who.int/prequal/info_applicants/procagencies/prequal_procagencies.htm.

- evaluation of product data and information submitted by manufacturers, including product formulation, manufacturing and test data and their results;
 - general understanding of the production and quality control activities of the manufacturers and suppliers and of their commitment to the principles of Good Manufacturing Practices (GMP);
 - assessment of consistency in the production processes and quality control activities through compliance with GMP, as described in the respective WHO publications¹⁷ and supplementary WHO GMP guidelines;
 - availability of appropriate quality systems and Standard Operating Procedures;
 - random sampling and testing of pharmaceutical products supplied;
 - adequate purchasing mechanisms (see WHO’s MQAS);
 - good Storage Practices (GSP);
 - good Distribution Practices (GDP);
 - monitoring of customers’ complaints and follow-up to remedy the shortcomings;
 - adequate handling of complaints and recalls; and
 - ongoing monitoring and re-qualification.
- d) The select criteria shall give priority to Contractors that comply at least with one of the following certifications or equivalent: EN46001/ EN46002, ISO13485/ ISO13488, Japan QS Standard for medical devices 1128, United States QS (21 CFR part 820), ISO9001/ISO9002, ISO9001/2000.
- e) Medical devices shall
- meet essential requirements as described by the Global Harmonization Task Force (GHTF)¹⁸;
 - be produced in conformity with ISO standards and/or other equivalent standards as recognised by the GHTF;
 - be marketing their products according to at least one of the regulatory authorities: MPALS License (Australia), Device License (Canada), CE Mark (EU), Device License (Japan), and 510 k Device Letter (USA).

¹⁷ “Quality assurance of pharmaceuticals: a compendium of guidelines and related materials”. WHO, Geneva, Volume 1 and 2 (Updated Edition), 1997 and “Good manufacturing practices and inspection”, WHO, Geneva, 2004.

¹⁸ 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.

- f) The references to international standards are neither exhaustive, nor definitive. Contracting Authorities shall take as a reference any internationally recognised standard that may be set and the updates and revisions of the standards mentioned herein.
- g) By derogation to paragraph 3.6, and irrespectively of the value of the contract to be awarded, the Contracting Authority shall launch a negotiated procedure by inviting simultaneously and in writing only pre-qualified candidates of their choice.

Whenever feasible¹⁹, the number of candidates invited shall be sufficient to ensure genuine competition.

- h) The Contracting Authority shall consult the International Drug Prices Indicator²⁰. When comparing the costs of pharmaceutical products, the cost of the whole treatment -not just the cost per unit- should be taken into consideration. Since the choice may also be influenced by other factors such as transportation charges, storage requirements and shelf-life, the total cost should be considered.

4.4. Food aid procurement rules and procedures

- (a) Priority shall be given, whenever it is possible and advisable having due regard to the context in which the Action is implemented and not disturbing deeply the local beneficiary markets, to purchases in the country of operation or neighbouring countries. The Contracting Authority shall acquire elements of evidence, based on local/ regional market analysis, that local/ regional procurement would not induce market distortions that could adversely affect vulnerable populations. The food aid products shall as much as possible match the nutritional habits of the beneficiary population.
- (b) The characteristics of the products and their packaging shall respect quality standards laid down in the domestic legislation of the country of origin and/or the country of destination, whichever legislation has the higher quality standard. Food products rejected due to failure to comply with this obligation are not eligible for Community funding.
- (c) By derogation to paragraph 3.4, second sub-paragraph, when the object of the contract is the supply of fresh food and the contract is divided into several lots taking into account the seasonal availability of products, each one of the lots

¹⁹ The market situation of each product, the nature of the medicines and medical equipment, and the critical dates for delivery may determine the numbers of candidates approached. Choices are restricted by the characteristics of medicines and medical equipment as some are either single-source or limited-source products. Other pharmaceutical products may be multi-source but effectively restricted to limited sources in many settings.

²⁰ 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 Contracting Authorities to compare prices.
<http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=english>

will be considered individually, and not aggregated, in order to establish the applicable threshold.

- (d) The contract notice shall specify, when required, the contractual Incoterms delivery conditions applied to the supply contract and identify the applicable Incoterm edition. When the Incoterms²¹ specified in the Contract Notice obliges the supplier to take out a transport insurance policy, this insurance shall be for at least the awarded tender amount and shall cover all risk associated with carriage.
- (e) When awarding contracts of a value of more than EUR 300,000, the Humanitarian Organisation shall contract, except in case of urgent Actions, a Monitoring Agency responsible for verifying and certifying the quantity, quality, packing and marking of supplies. The Humanitarian Organisation shall include in the tender and contractual documents the necessary provisions as to assure the right of access and monitoring of the Monitoring Agency.
- (f) Contracts concluded by the Contracting Authority shall include provisions on the accepted tolerance for weight and/or quantities delivered and identify the procedure for establishing reductions of price for quality deviations and deliveries beyond the contracted delivery date or period.

4.5. Pre-established stocks

The Contracting Authority or its Implementing Partners may incur expenditure before the date of submission of the Action proposal and related to the constitution of stocks of goods and equipment for use in connection with the Action for which the contribution is awarded. This expenditure is eligible for Community financing²² provided that the procurement rules of the Contracting Authority had been correctly applied and with due regard to the Mandatory Principles set out in Chapter 2 herein.

4.6. Framework Contracts

Framework Contracts may be concluded with one or several Contractors. A Framework Contract with several Contractors may take the form of contracts which are separate but concluded in identical terms. The Contracting Authority has in any case to comply with the mandatory principles established in chapter 2 herein for the award procedure of the Framework Contract. For the purposes of calculating the estimated amount of a Framework Contract, the value to be taken into account shall be the maximum value of all the contracts envisaged during the total lifetime of the Framework Contract.

Framework Contracts may not be used in such a way as to prevent, restrict or distort competition. In sectors subject to a rapid price and technological evolution, Framework Contracts without reopening of competition shall contain a stipulation

²¹ Cf. www.iccwbo.org/incoterms/id3042/index.html

²² Cf. Article 171 (a) of the IRFR

either on a mid-term review or on a benchmarking system. The term of a Framework Contract may not exceed five years.

Specific contracts based on Framework Contracts shall be awarded in accordance with the terms of the Framework Contract, after having consulted in writing all Contractors originally part of the Framework Contract.

4.7. Humanitarian Procurement Centres (HPCs)

In accordance with the procedure set out in the Humanitarian Aid Guidelines for Procurement, the European Commission Directorate General for Humanitarian Aid (DG ECHO) shall assess the procurement rules and procedures, the financial and the operational capabilities of those entities wishing to be recognised as HPC and shall maintain a registry accessible via internet of validated HPCs.

HPCs shall guarantee equal treatment of suppliers and among Contracting Authorities, high standards for integrity, transparency, price, performance and quality. The procurement procedures of HPCs shall comply with the mandatory principles of procurement set out in Annex IV.

The handling fee or overhead costs charged to the Contracting Authority may be considered eligible providing that the HPC is able to demonstrate the methodology used. This methodology will be verified by DG ECHO as part of the HPC's validation process. The contractual arrangements concluded between the Contracting Authority and the Humanitarian Procurement Centre shall include the necessary provisions in this respect and shall allow the identification of the different costs.

Contracting Authorities may place orders with a HPC on the basis of a negotiated procedure with a single tender.

There is no contractual relation between the European Commission and the HPC. The validation by the European Commission of an organisation as HPC does not constitute an assurance with respect to the quality of products and services provided by the HPC or with respect to the latter's compliance with contractual obligations towards third parties. The Contracting Authority shall exercise the necessary degree of care, efficiency and diligence when procuring supplies or services from a HPC.

HPCs shall grant the European Commission, the European Anti-Fraud Office and the Court of Auditors, appropriate right of access to their financial and accounting documents for the purposes of checks and audits.

Without prejudice to the adoption of financial and administrative sanctions in accordance with the applicable Legislative provisions, the European Commission shall cancel an entry in this registry, after having given the concerned HPC the opportunity to present its observations, in cases of failure to comply with the mandatory principles of procurement, in particular in cases of corrupt, fraudulent, collusive or coercive practices, and when the HPC fails to meet its contractual obligations with Contracting Authorities.

5. FINAL PROVISIONS

5.1. Derogations to the General Rules and Procedures

Any departure from the General Rules and Procedures established in Annex IV is subject to written approval from the European Commission, which shall deal expeditiously with any request accompanied with proper justification, and will be included in the Special Conditions of the Agreement.

Derogations from these rules shall be funded on security, operational, technical or quality reasons; shortfall or unavailability on the markets of the supplies; costs or delays due to transport; on the grounds of legislation in the country of operation or if the fulfilment of the contractual obligation would harm the Humanitarian Organisation's mandate or the safety of its staff.

5.2. Interpretation

The terms used in Annex IV and in the Humanitarian Aid Guidelines for Procurement shall have the same meaning as attributed to them in glossaries, fact sheets or any other supporting documents which may be drafted by the European Commission's Directorate General for Humanitarian Aid (DG ECHO). In case of any discrepancy or inconsistency between the supporting documents and Annex IV, the latter shall take precedence.

All mentions made to Council or Commission Regulations should be understood as referring to the most recent applicable version of the legislative text as published in the Official Journal of the European Union. The European Commission will inform Humanitarian Organisations on the application of any relevant modification of the mentioned Regulations. If required by the substance of the modification, references to European legislation will be updated by means of amendments.

Headings in Annex IV have no legal significance and do not affect its interpretation.

5.3. Contractual and regulatory sanctions

The European Commission may suspend the payment period established in the Agreement following presumed infringements of the procurement rules and procedures in order to verify whether a substantial irregularity or fraud have actually occurred.

In the event of breach of the Mandatory Principles, and when applicable, of the rules or procedures established in Annex IV, the European Commission reserves its right to terminate with immediate effect the Agreement signed with the Contracting Authority and to consider any expenditure incurred by the Contracting Authority related to the contracts in question not eligible for Community financing.

This is without prejudice to the adoption of financial and administrative sanctions in accordance with the relevant Legislative Provisions²³, in particular in cases where the

²³ See in particular, Articles 96, 114 (4) of the FR and Articles 134 (b) and 175 IRFR.

Contracting Authority has been found in serious breach of its obligations, is found guilty of involvement in corrupt, fraudulent, coercive or collusive practices or when the Contracting Authority deliberately destroys, falsifies, alters or conceals evidence referred to Contracts in order to hamper investigations into allegations of procurement mismanagement.