

DECREE-LAW No. 12 /2016
of 11 May 2009
FIRST AMENDMENT TO
DECREE-LAW No. 2/2009 OF 15 JANUARY
SPECIAL PROCUREMENT LEGAL REGIME FOR THE AUTONOMOUS SERVICE OF
MEDICINES AND HEALTH EQUIPMENT, E.P. (SAMES)

The Government Decree-Law No. 2/2009 of 15 January 2009, which approves the Special Procurement Legal Regime for the Autonomous Service of Medicines and Health Equipment, E.P. (SAMES, E.P.) aims to establish specific rules for the procurement of medicines, medical supplies and medical-hospital equipment, mainly for the National Health Service.

In order to make more efficient the procurement system for the supply of medicines, medical inputs and medical-hospital equipment, as well as their conservation and distribution to the National Health Service entities, the Government, by Decree-Law No. 19/2015 and Decree-Law No 18/2015, both of 24 June, first extinguished SAMES, in all its rights and assets.

In view of the new institutional reality, it becomes urgent to amend Decree-Law no. 2/2009 of 15 January.

Thus, the Government decrees, in accordance with Article 115(3) of the Constitution of the Republic, to be enforced as law, the following:

Article 1
Amendments to Decree-Law No. 2/2009 of 15 January 2009

Articles 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 15, 22, 23, 26, 38, 45, 46, 47, 52, 53, 55, 56 and 58 of Decree-Law No. 2/2009 of 15 January 2009 shall be replaced by the following:

"Article 1
(...)

Without prejudice to the application of the general principles spelled out in Decree-Law No. 10/2005, of 21 November, the purpose of this law is to establish special procedures for the procurement of medicines, medical supplies and medical-hospital equipment necessary for operations of the National Health Service.

Article 2
(...)

1. The scope of application of the present document covers the procurement procedures performed by SAMES, with its own budget or made available by the other entities of the National Health Service, or through bilateral and multilateral funds.
2. The present legal diploma is applicable, with due variations, to the procedures for the procurement of medicines, medical supplies and medical-hospital equipment, carried out centrally by the Ministry of Health or by the other entities of the National Health Service, in emergency situations, by means of a previous statement of SAMES, of lack of capacity to meet, at the moment, such needs.

Article 3
(...)

The following entities have the power to authorize procurement procedures and sign the respective contracts:

- a) The Executive Director of SAMES, in all procedures carried out by SAMES, regardless of the amount;.
- b) In emergency purchases:
 - i. The Minister of Health, for procedures performed centrally by the Ministry of Health;
 - ii. Top managers of the National Health Service Hospitals and the National Health Laboratory.

Article 4

(...)

1. The Executive Director of SAMES may delegate, in writing, the power to authorize procurement procedures, to one of the directors of SAMES.
2. The Officer who receives the delegation of powers may not subdelegate.
3. The Executive Director is not exonerated from the responsibility of compliance with the law in each one of the procurement procedures that are made by the directors to whom he/she has delegated.

Article 5

(...)

1. It is incumbent on the Procurement Service of SAMES to proceed with the procurement of medicines, medical supplies and medical-hospital equipment, in coordination with the relevant services and in accordance with the procedures determined by the responsible entity, namely:
 - a) (...)
 - b) To forward to the responsible authorities complaints resulting from the tenders;
 - c) (...);
 - d) (...);
 - e) (...);
 - f) (...).
2. The Procurement Department is also responsible for:
 - a) (...);
 - b) (...);
 - c) (...);
 - d) (...);
 - e) (...);
 - f) (...);
 - g) (...).

Article 6

Powers of the SAMES Executive Board

As regards procurement, the SAMES Executive Board has the following powers:

- a) (...);
- b) Decide on complaints and appeals submitted by competitors;
- c) (...);
- d) (...);
- e) Ratify the list of pre-qualified suppliers.

Article 8

(...)

1. (...).
2. (...).
3. Only SAMES' pre-qualified competitors are qualified to participate in procurement procedures without tender procedures, to be carried out by the entities of the National Health Service, within the scope of the present legal diploma.
4. Suppliers of medicines, medical inputs and medical-hospital equipment, pre-qualified by WHO, UNICEF and other UN Agencies, may be included in the list of pre-qualified ones by SAMES, through a simplified pre-qualification procedure.

Article 9

(...)

1. (...).
2. In public tender and in all subsequent procedures, the currency in legal tender in the RDTL¹ shall be used.

¹ RDTL – Democratic Republic of Timor-Leste.

Article 10

(...)

1. (...).
2. (...).
3. In restricted tender and in all subsequent procedures, the currency in legal tender in the RDTL shall be used.

Article 11

(...)

1. (...).
2. (...).
3. In the procurement procedure by request of quotations, the legal currency in legal tender in the RDTL must be used.

Article 12

(...)

1. (...).
 - a) Where there is only one provider of medicines, medical supplies and medical-hospital equipment without any other reasonable alternative or substitute;
 - b) When there is an ombudsman who has specific exclusive rights in relation to certain medicines, medical inputs and medical-hospital equipment, without any other reasonable alternative or substitute;
 - c) (...);
 - d) (...);
 - e) (...);
 - f) In cases of additional supply of medicines or parts of medical-hospital equipment by a competitor whose offer has already been accepted, in another signed contract and, in which the substitution of the supplier would result in the procurement of goods that do not meet adaptability or compatibility requirements.
2. In cases of direct adjudication for emergency circumstances, SAMES must purchase only those medicines, medical supplies and medical-hospital equipment that are strictly necessary to remedy the emergency situation and meet the immediate needs in the face of the emergency:
 - a) (...);
 - b) (...).
3. In the procurement procedure by direct adjudication, the currency in legal tender in the RDTL should be used.

Article 13

(...)

1. The choice of procedure shall be determined taking into account the value of acquisition, classification of medicines, medical supplies and medical-hospital equipment, depending on the National List of Medicines, being strictly prohibited the conduct consisting in dividing the amount of the actual cost of the purchase, in several instalments, so that none of them reaches the limits of the established amounts.
2. (...).
3. (...).
4. Division of medicines, medical supplies and medical-hospital equipment, according to the classification provided for in the National List of Medicines, for the purposes of procurement, does not constitute a violation of the principle of unity of expenditure.

Article 15

(...)

1. (...):
 - a) (...);
 - b) (...);
 - c) (...);
 - d) The medicines, medical inputs and medical-hospital equipment whose supply is subject to pre-qualification, including general requirements of quantity and quality;

- e) (...);
 - f) (...);
 - g) (...);
 - h) (...);
 - i) (...).
2. (...):
- a) (...);
 - b) (...).

Article 22

(...)

1. (...).
2. (...):
- a) (...);
 - b) (...);
 - c) (...);
 - d) (...);
 - e) (...).
3. (...):
- a) All notices must be published in at least one national newspaper in one of the official languages and in English;
 - b) (...);
 - c) Without prejudice to the provisions of the previous paragraphs, announcements should be published on the Government's Procurement Portal and, in other electronic or printed international media.
4. (...).
5. (...).

Article 23

(...)

1. (...):
- a) (...);
 - b) Characteristics of the medicines, medical consumer goods and medical equipment, in particular, quantity, dosage, requisite quality, packaging and other specific characteristics;
 - c) (...);
 - d) (...);
 - e) (...);
 - f) (...);
 - g) (...);
 - h) (...);
 - i) (...);
 - j) (...);
 - k) (...);
 - l) (...);
 - m) (...).
2. (...).

Article 26

(...)

1. The deadlines for submission of tenders shall be as follows:
- a) Between forty-five and sixty days for public tenders, counted from the date of issue of the tender documents;
 - b) Between fifteen and forty-five days for restricted tenders, counted from the date of the invitations.
2. (...).
3. (...).

Article 38

(...)

1. The Standing Committee on the Evaluation of Proposals, hereinafter called CPAP, shall be appointed by the Minister of Health, upon SAMES' Executive Director's proposal, for a period of 12 months, and shall consist of three or five full members and three alternates, one of whom shall be appointed Chairman and one of his/her alternates, in the event of absence and impediment.
2. The members of CPAP are designated from among SAMES employees, and include at least two employees of the Ministry of Health's central services, one permanent and one substitute, with knowledge in the pharmaceutical area and/or medical-hospital equipment.

Article 45

(...)

1. (...).
2. The list of pre-qualified competitors must be drawn up and the minutes of the procedure with the respective individual foundations signed by the members of the CPAP who participated in the procedure, valid as a final report, to be delivered to the Executive Board within a maximum period of three days, counting from the date of conclusion of the evaluation, for ratification.
3. In case the list of pre-qualified members is approved, it is sent to the Procurement Service for publication. If not, it is returned, with due justification, to the CPAP, for re-evaluation.
4. The list referred to in the previous number is published under the terms established in article 49 of the present legal diploma.

Article 46

(...)

1. (...):
 - a) (...);
 - b) (...);
 - c) (...).
2. (...):
 - a) (...);
 - b) The quality of medicines, medical supplies and medical-hospital equipment;
 - c) The specifications and quality guarantees of medicines, medical supplies and medical-hospital equipment;
 - d) (...);
 - e) (...).
3. (...).
4. (...).
5. (...).
6. The CPAP shall complete the evaluation of proposals and present the report to the Executive Board within fifteen days from the date of opening of the proposals.

Article 47

Analysis by the Executive Board of SAMES

1. The report of the current procedure shall be delivered to the Chairperson of the Executive Board within three days after its conclusion and the Executive Board shall decide within a maximum of five days.
2. If the decision of the CPAP is ratified, the recommendation must be sent to the Procurement Service to process the contract.
3. If the decision of CPAP is rejected, the Executive Board must state the reasons for its decision and refer it to the CPAP for further analysis.
4. In the cases foreseen in the previous number, the CPAP can propose the second qualified competitor and so on successively or, propose to the Board the realization of a new procedure.

Article 52

(...)

1. CPAP must receive submitted complaints and decide about their admission, within a maximum period of five days, and submit them to the Executive Director or to entity whereby the power is delegated, to authorize the procurement procedure in complaint.
2. (...).
3. (...).
4. The Executive Director of SAMES or the one to whom the power to authorize the procurement procedure in complaint is delegated, may suspend the procedure for a period of five days, extendable for the same period, if there are reasons that justify it.
5. As long as there is no decision in transit in administrative procedures relative to the complaint or to the hierarchical appeal, the adjudication cannot be made in all the procedures.

Article 53

(...)

1. After analyzing the case, the Executive Director or the entity to whom the power to authorize the procurement procedure in complaint is delegated, after hearing the Executive Board of SAMES, must decide whether to accept or reject the complaint presented, within a period of five days.
2. (...).

Article 55

(...)

1. In the procedures by request for quotations, the invitation, duly signed by the Executive Director of SAMES is addressed to at least three suppliers already known by SAMES or selected in advance by the pre-qualification procedure, attaching the quotation document, which must contain at least:
 - a) The list of medicines, medical supplies and medical-hospital equipment, specifying their quantity and quality;
 - b) (...);
 - c) (...);
 - d) (...).
2. (...).
3. The choice made in accordance with the previous number shall be submitted to the Executive Board of SAMES for ratification.
4. (...).
5. (...).
6. (...).
7. The participants in the procedure for requests for quotations not in conformity with the response of the CPAP may lodge a hierarchical appeal with the Executive Director of SAMES who, after hearing the Executive Board, must respond within three days.
8. The Executive Director's response constitutes the final response.

Article 56

(...)

1. In procedures by direct adjudication, SAMES may address one or certain suppliers to meet specific supply needs.
2. After verifying the existence of special circumstances, foreseen in paragraphs 1 and 2 of Article 12, the Executive Director of SAMES submits to the Executive Board, for ratification, the list of medicines, medical supplies and medical-hospital equipment, as well as detailed information of one or more specific suppliers to be chosen.
3. After ratification by the SAMES Executive Board, the Procurement Service processes the contract with the chosen supplier.

Article 58
Subsidiary Regime

The general norms in terms of procurement and public contracts apply in everything that does not contradict the provisions of the present document".

Article 2
Addition

Articles 8-A, 19-A, Section V in Chapter IV and Articles 37-A and 37-B are added to Decree-Law No. 2/2009 of 15 January 2009, with the following wording:

"Article 8-A
Formalities

1. One of the official languages or the English language shall be used in the procurement procedures.
2. Whenever the English language is chosen, the corresponding translated version of the documents and contract in one of the official languages shall be added to the file.

Article 19-A
Simplified pre-qualification procedure

The simplified pre-qualification procedure consists of the invitation, formulated by SAMES, and its acceptance by suppliers of medicines, medical supplies and medical-hospital equipment, pre-qualified according to the list of WHO and other institutions of the United Nations, to join the pre-qualified list in SAMES.

Section V
Commission for the Opening of Envelopes

Article 37-A
The Appointment

1. The Opening Committee, hereinafter called CAI, is appointed by the Executive Director of SAMES before the start of the pre-qualification or tender procedures, for a period of one year, without the possibility of renewal.
2. CAI must be composed of at least three SAMES employees, one of whom is appointed its chairperson.

Article 37-B
Public Act of Opening of the Envelopes

1. On the day set in the pre-qualification documents or in the tender documents, in a public act, CAI will open the envelopes.
2. Any interested parties may attend the public act, without the intervention of those present being allowed.
3. In the pre-qualification procedures, the act begins with the reading of the identification of procedure, proceeding to the opening of the envelopes and, immediately afterwards, the list of competitors is made, in sight of all those present, taking a copy of this list in a document that must be signed by two witnesses chosen from among those present in the public act, preferably from among the competitors, and by the members of the CAI present.
4. In a public tender, the act begins with the reading of the identification of procedure, followed by the opening of the envelopes and, immediately thereafter, the list of competitors is made, with the prices offered, which is written in front of all present and read aloud, taking a copy of this list in a document that must be signed by two witnesses chosen from among those present in the public act, preferably from among the competitors, and by the members of the CAI present.
5. In the pre-qualification or bidding procedures, right after the public act, CAI gathers all documents, delivering them to the Standing Committee for Evaluation of Bids, or keeping them in a safe place until they are delivered to the said Committee.
6. CAI shall deliver to the Standing Committee on the Evaluation of Proposals, all documents, at the latest, on the day following the opening."

Article 3

Repeal

Article 39(a) and Article 41, all of Decree-Law No. 2/2009 of 15 January 2009, are hereby repealed.

Article 4

Republishing

Decree-Law No. 2/2009 of 15 January 2009, as amended by this Decree-Law, is republished as an Annex.

Article 5

Entry into force

This Decree-Law shall enter into force on the day following its publication.

Approved by the Council of Ministers on January 27, 2016.

The Prime Minister,

Dr. Rui Maria de Araújo

The Minister of Health,

Maria do Céu S. Pina da Costa

Enacted on 11 - 04 - 2016

Be it published.

The President of the Republic

Taur Matan Ruak

ANNEX

DECREE LAW No. 2/2009

**SPECIAL PROCUREMENT LEGAL REGIME FOR THE AUTONOMOUS SERVICE OF
MEDICINES AND HEALTH EQUIPMENT, E.P. (SAMES)**

Decree-Law no.10/2005, of November 21, 2005, creating the Legal Procurement Regime, determines that a special legal procurement regime shall be established at SAMES, to ensure that this State-Owned Enterprise, set up by Government Decree no. 2/2004, of April 21, 2004, may properly perform the functions laid down in its Articles of Association.

Thus, the Government, pursuant to Article 115, number 3 of the Constitution of the Republic and of Article 106 of Decree-Law No. 10/2005, of November 21, 2005, establishes the following to be enforced as law.

**CHAPTER I
GENERAL PROVISIONS****SECTION ONE
GENERAL PROVISIONS****Article 1
Objective**

Without prejudice to the application of the general principles spelled out in Decree-Law No. 10/2005, of 21 November, the purpose of this law is to establish special procedures for the procurement of medicines, medical supplies and medical-hospital equipment necessary for operations of the National Health Service.

**Article 2
Scope of Application**

1. The scope of application of the present document covers the procurement procedures performed by SAMES, with its own budget or made available by the other entities of the National Health Service, or through bilateral and multilateral funds.
2. The present legal diploma is applicable, with due variations, to the procedures for the procurement of medicines, medical supplies and medical-hospital equipment, carried out centrally by the Ministry of Health or by the other entities of the National Health Service, in emergency situations, by means of a previous statement of SAMES, of lack of capacity to meet, at the moment, such needs.

**SECTION TWO
POWERS IN THE PROCUREMENT PROCEDURE****Article 3
Entity competent for authorizing procurement procedures**

The following entities have the power to authorize procurement procedures and sign the respective contracts:

- a) The Executive Director of SAMES, in all procedures carried out by SAMES, regardless of the amount;
- b) In emergency purchases:
 - i. The Minister of Health, for procedures performed centrally by the Ministry of Health;
 - ii. Top managers of the National Health Service Hospitals and the National Health Laboratory.

Article 4
Delegation of powers

1. The Executive Director of SAMES may delegate, in writing, the power to authorize procurement procedures, to one of the directors of SAMES.
2. The Officer who receives the delegation of powers may not subdelegate.
3. The Executive Director is not exonerated from the responsibility of compliance with the law in each one of the procurement procedures that are made by the directors to whom he/she has delegated.

Article 5
Powers of the Supply Department of SAMES

1. It is incumbent on the Procurement Service of SAMES to proceed with the procurement of medicines, medical supplies and medical-hospital equipment, in coordination with the relevant services and in accordance with the procedures determined by the responsible entity, namely:
 - a) Prepare the tender papers, manage their public announcement and subsequent diligences;
 - b) To forward to the responsible authorities complaints resulting from the tenders.
 - c) Announce awarding intentions.
 - d) Process claims resulting from the awarding.
 - e) Prepare oncontract papers.
 - f) Manage contract execution, in co-ordination with the relevant departments.
2. The Procurement Department is also responsible for:
 - a) Prepare the annual supply plan of SAMES and secure its compliance;
 - b) Create and keep the vendor record, containing a vendor list by area of expertise, as well as information on each vendor's performance;
 - c) Manage correspondence with bidders and vendors;
 - d) Hold periodical meetings with other relevant departments, with a view to promoting the rules in force governing supply;
 - e) Recommend to competent authorities within SAMES the appropriate supply procedures, so as to secure the best cost-to-quality-to-quantity relationship;
 - f) Propose punishing measures to be imposed on people who infringe the rules governing the present supply system;
 - g) Keep, for a five-year period, all papers concerning the supply operations.

Article 6
Powers of the SAMES Executive Board

As regards procurement, the SAMES Executive Board has the following powers:

- a) Analyze the tender reports and approve the contract awarding bids;
- b) Decide on complaints and appeals submitted by competitors;
- c) Monitor contract execution;
- d) Make decisions regarding the punishing measures against people who infringe the rules governing the present supply system.
- e) Ratify the list of pre-qualified suppliers.

**CHAPTER TWO
SUPPLY PROCEDURES**

**SECTION ONE
TYPES OF PROCEDURE**

**Article 7
Procurement procedures**

SAMES accepts the following types of procedure:

- a) Open tendering, mandatory for contracts exceeding 1 million USD, to which any party may submit a bid, provided that they meet the requirements laid down in the tender papers;
- b) Partial invitation, for contracts equal to or lower than 1 million US and higher than 500,000 USD, to which only the invited competitors may submit bids;
- c) Request for quotations, for contracts under 500,000 USD;
- d) Contract by direct agreement in exceptional cases, irrespective of the contract amount.

**Article 8
Pre-qualification procedure**

1. SAMES shall launch a pre-qualification procedure to identify and select, in the framework of a preliminary analysis, which competitors meet the requirements previously laid down in the pre-qualification papers.
2. The pre-qualification procedure may be launched on yearly basis, prior to the launching of the supply procedures by partial invitation and request for quotations.
3. Only SAMES' pre-qualified competitors are qualified to participate in procurement procedures without tender procedures, to be carried out by the entities of the National Health Service, within the scope of the present legal diploma.
4. Suppliers of medicines, medical inputs and medical-hospital equipment, pre-qualified by WHO, UNICEF and other UN Agencies, may be included in the list of pre-qualified ones by SAMES, through a simplified pre-qualification procedure.

**Article 8-A
Formalities**

1. One of the official languages or the English language shall be used in the procurement procedures.
2. Whenever the English language is chosen, the corresponding translated version of the documents and contract in one of the official languages shall be added to the file.

**SECTION TWO
TENDERS**

**Article 9
Open tendering**

1. SAMES shall launch the open tendering procedure for contracts exceeding the amount of 1 million USD, with a view to promoting the participation of national and international competitors.
2. In public tender and in all subsequent procedures, the currency in legal tender in the RDTL shall be used.

Article 10
Partial invitation

1. SAMES shall launch the partial invitation procedure by extending an invitation to all suppliers selected by way of the pre-qualification procedure.
2. Partial invitation is mandatory in acquisitions between 500,000 and 1,000,000 USD.
3. In restricted tender and in all subsequent procedures, the currency in legal tender in the RDTL shall be used.

Article 11
Supply by Request for Quotations

1. SAMES shall launch the Request for Quotations procedure, without tender formalities, by extending an invitation to at least three suppliers previously known by SAMES, or selected in advance by way of the pre-qualification procedure.
2. The request for quotations procedure may be used whenever the contract amount is lower than 500,000 USD.
3. In the procurement procedure by request of quotations, the legal currency in legal tender in the RDTL must be used.

Article 12
Supply by Direct Agreement

1. Supply by direct agreement is an exceptional procedure, whereby SAMES, without launching tender procedures, may address one or more suppliers to meet specific supply requirements, provided that the following special circumstances apply:
 - a) Where there is only one provider of medicines, medical supplies and medical-hospital equipment without any other reasonable alternative or substitute;
 - b) When there is an ombudsman who has specific exclusive rights in relation to certain medicines, medical inputs and medical-hospital equipment, without any other reasonable alternative or substitute;
 - c) When SAMES, after launching twice the procedures for open tendering, or partial invitation, or request for quotations, failed to receive bids that fulfilled the awarding criteria;
 - d) In the case of emergency supplies;
 - e) In cases of additional supply of unforeseen quantities, by a competitor whose offer had been previously accepted, in the framework of another signed contract.
 - f) In cases of additional supply of medicines or parts of medical-hospital equipment by a competitor whose offer has already been accepted, in another signed contract and, in which the substitution of the supplier would result in the procurement of goods that do not meet adaptability or compatibility requirements.
2. In cases of direct adjudication for emergency circumstances, SAMES must purchase only those medicines, medical supplies and medical-hospital equipment that are strictly necessary to remedy the emergency situation and meet the immediate needs in the face of the emergency:
 - a) Existence of an urgent unforeseeable need, being not practical to launch tender procedures or request for quotations;
 - b) Official declaration of disaster, or other requirements compelling urgent action in the public interest;
3. In the procurement procedure by direct adjudication, the currency in legal tender in the RDTL should be used.

**SECTION THREE
PROCEDURE SELECTION**

**Article 13
Selection criteria**

1. The choice of procedure shall be determined taking into account the value of acquisition, classification of medicines, medical supplies and medical-hospital equipment, depending on the National List of Medicines, being strictly prohibited the conduct consisting in dividing the amount of the actual cost of the purchase, in several instalments, so that none of them reaches the limits of the established amounts.
2. The selected procedure should be the most appropriate for meeting the supply requirements and securing the best cost-to-quality-to-quantity ratio.
3. The open tendering procedure should be given preference, whenever possible.
4. Division of medicines, medical supplies and medical-hospital equipment, according to the classification provided for in the National List of Medicines, for the purposes of procurement, does not constitute a violation of the principle of unity of expenditure.

**CHAPTER THREE
STEPS IN THE PRE-QUALIFICATION PROCEDURE**

**Article 14
Start-up**

1. The pre-qualification procedure starts with the publication of the pre-qualification notice, inviting all potential competitors to bid.
2. The pre-qualification procedure shall comply with the standard tender procedure rules.

**Article 15
Requirements of pre-qualification notices**

1. Every pre-qualification notice should contain the following information:
 - a) SAMES address and contacts of the entity in charge of processing the bids;
 - b) Place and date of notice issue and authorizing authority;
 - c) Declaration that this is a pre-qualification notice, fulfilling all other legal requirements;
 - d) The medicines, medical inputs and medical-hospital equipment whose supply is subject to pre-qualification, including general requirements of quantity and quality;
 - e) Schedule of the pre-qualification procedure, the means to obtain the prequalification papers and the place where the latter can be obtained;
 - f) Price, if there is one, charged by SAMES for the pre-qualification papers and forms;
 - g) Languages in which the papers are available;
 - h) Place and deadlines for submitting the pre-qualification papers;
 - i) Date of notification of the pre-qualification outcome.
2. Pre-qualification notices should not request or receive from the competitors any information concerning:
 - a) Price bid;
 - b) Any other information that may obstruct the on-equal-foot participation of the competitors.

Article 16

Pre-qualification papers

1. In the pre-qualification procedure, pre-qualification papers shall be provided to all competitors so that they can submit the required data.
2. Pre-qualification papers should include, at least:
 - a) Instructions on the preparation and submission of pre-qualification requests;
 - b) Summary of the main general terms and conditions of the contract to be signed;
 - c) Any documentary evidence, or other information, that should be submitted by competitors to prove their qualifications.
3. Pre-qualified competitors should continue to meet the pre-qualification requirements and make them available in the forms and opportunities that may be requested by SAMES.

Article 17

Amendments to pre-qualification notices

1. SAMES may amend the pre-qualification papers up to the third day before the deadline established for pre-qualification bid submission, if there are exceptional reasons accounting for such procedure. The said amendments should be made public in terms and conditions identical to those of the pre-qualification notice.
2. The deadline for submitting the pre-qualification bids may be extended, if necessary.

Article 18

Clarifications on pre-qualification papers

1. Competitors have the right to request, in writing, clarifications to SAMES on the pre-qualification papers, in the period laid down in the pre-qualification papers.
2. Once a request has been received pursuant to the foregoing paragraph, SAMES should answer as soon as possible.
3. Answers to any requests that may be of interest to other competitors should be reported to all of those whom SAMES has supplied the pre-qualification, without identifying the source of the request.

Article 19

Additional verification on pre-qualification requirements

1. The jury may exceptionally require an already qualified competitor to prove his qualifications once more, according to the same criteria adopted in prequalification, assigning him a deadline to make such proof.
2. In this case the final deadline established for completing the pre-qualification procedure should be extended and such extension should be communicated to all competitors.
3. A competitor who cannot again make proof of his qualifications, when requested to do so, should be declassified.
4. If the foregoing paragraph applies, the jury has the obligation of promptly notifying each competitor who has been asked to make new proof of his qualifications to do it in satisfactory terms.

Article 19-A

Simplified pre-qualification procedure

The simplified pre-qualification procedure consists of the invitation, formulated by SAMES, and its acceptance by suppliers of medicines, medical supplies and medical-hospital equipment, pre-qualified according to the list of WHO and other institutions of the United Nations, to join the pre-qualified list in SAMES.

Article 20

Validity of pre-qualification requirements

The pre-qualified competitors should continue to meet the pre-qualification requirements and make them available in the forms and opportunities that may be requested by SAMES.

CHAPTER FOUR

STAGES IN THE TENDER PROCEDURE

SECTION ONE

STANDARD RULES OF PROCEDURE

Article 21

Tender stages

Supply by tender procedure has the following stages:

- a) Opening and publication;
- b) Preliminary conference;
- c) Reception of bids;
- d) Public session in which the jury opens the bid envelopes;
- e) Rejection or admission of competitors by the jury;
- f) Assessment, selection and classification of competitors by the jury;
- g) Intention to award the contract made public;
- h) Deadline for competitors to submit claims;
- i) Signature of contract.

SECTION TWO

OPENING AND PUBLICATION

Article 22

Opening and publication of tender notices and invitations

1. Tender opening is the procedural stage in which SAMES, by notice or invitation, calls upon all potential suppliers to submit their bids for evaluation.
2. Tender notices should at least include the following:
 - a) SAMES address, place, date of issue and authority authorizing the tender;
 - b) Declaration stating that this is a notice inviting tender;
 - c) Address, schedule and timetable for acquiring the tender papers;
 - d) Dates established for each tender stage, from invitation to contract signature;
 - e) Factors to be taken into account for evaluation purposes and, whenever possible, the form in which they will be quantified.
3. Publication of notices shall comply with the following rules:
 - a) All notices must be published in at least one national newspaper in one of the official languages and in English;
 - b) Notices shall be sent simultaneously to all the media on which their publication is scheduled;
 - c) Without prejudice to the provisions of the previous paragraphs, announcements should be published on the Government's Procurement Portal and, in other electronic or printed international media.
4. In partial invitations the notice is replaced by the invitation addressed to previously selected suppliers, which SAMES may decide to publish or not, attaching the tender papers thereto.
5. The entity competent for launching the procedure should sign the notice or invitation.

Article 23
Tender papers

1. Tender papers on bid submission should include at least the following information:
 - a) Instructions for preparing and submit bids;
 - b) Characteristics of the medicines, medical consumer goods and medical equipment, in particular, quantity, dosage, requisite quality, packaging and other specific characteristics;
 - c) Technical quality guarantee papers;
 - d) Price bids in a separate envelope;
 - e) Date and place anticipated for fulfilling the commitments;
 - f) Methods and procedures for evaluation the qualifications of the competitors;
 - g) Conditions for assuring the validity of the offer, as regards both issuer and nature, form, amount and period of validity, and mode of fulfilment;
 - h) Conditions for assuring performance, as regards both issuer and nature, form, amount and period of validity, and mode of fulfilment;
 - i) Any other information which, according to SAMES, can be usefully provided in connection with the tender;
 - j) Summary on the main terms and conditions required by the contract to be signed, not included in the pre-qualification procedure, if applicable;
 - k) Any documentary evidence or other information that should be submitted by the competitors to prove their qualifications and the remaining requirements, if no pre-qualification procedure was launched;
 - l) Instrument drawn up by a notary-public authorizing the person who submits the bid to be obliged on behalf of the competitor, if such capacity is not demonstrated by the other bid papers;
 - m) Any other papers required for proving that the specific requirements imposed by SAMES are met.
2. The price of these papers should reflect only the cost associated with their printing and distribution to the competitors.

Article 24
Preliminary conference

1. SAMES may hold a preliminary conference for providing all clarifications regarding the tender.
2. The preliminary conference is open to the public.
3. No verbal instructions given during the conference shall be binding, inasmuch as they may modify the contents of the tender papers.
4. When it is necessary to amend or modify the terms of the tender as a result of a preliminary conference, such decision should be taken later on by SAMES and simultaneously communicated in writing to all competitors.

SECTION THREE
RECEPTION OF BIDS

Article 25
Key elements of the bids

1. Bids should meet the requirements laid down in the tender papers.
2. The price shall be given in figures, followed by the amount expressed in full, the latter prevailing in case of differences.

Article 26
Bid delivery deadline

1. The deadlines for submission of tenders shall be as follows:
 - a) Between forty-five and sixty days for public tenders, counted from the date of issue of the tender documents;
 - b) Between fifteen and forty-five days for restricted tenders, counted from the date of the invitations.
2. SAMES may extend the deadline initially established for an appropriate period of time, when there are grounds for it.
3. Deadline extensions should be promptly and simultaneously communicated to all competitors.

Article 27
Bid delivery and registration

1. Bids shall be delivered directly or by registered mail and received within the established deadline, at the place or places indicated for their delivery.
2. If the notice or invitation indicates such possibility, bids may be sent by other modes of communication, namely fax or e-mail, whenever such procedure is appropriate and feasible as a function of the volume or type of papers.
3. In the case of the foregoing paragraph, paper acceptance shall depend upon the requirements established in the rules and procedures in force for governing electronic trade.
4. The reception of each bid should be registered by noting down on the respective wrapper (i.e. package or envelope) the date and time of arrival and the sequence number of their submission.
5. The received bids should be kept in a safe place with restricted access, open only to authorized personnel.

Article 28
Submission

1. Each competitor may only submit one bid.
2. Each competitor shall pay for the costs incurred in connection with bid presentation and submission, irrespective of the outcome of the tender.
3. The bid shall be submitted in individual opaque, closed and separate wrappers, following the instructions provided in the tender papers.

Article 29
Bid validity period

1. The period of validity of the bids should be enough to allow for their comparison and evaluation, as well as to ensure all approvals required with a view to having the contract signed within the said period.
2. Competitors should submit a bid, and a tendering security, that shall remain valid for the period indicated in the tender papers.

Article 30
Extension of the bid validity period

1. SAMES may request the competitors, exceptionally and before the bid validity period expires, to extend the validity of their bids for a period up to four weeks.
2. Competitors have the right to refuse such request without losing their tendering security, but the validity of their bid will expire on the initially set date.
3. Competitors who accept to have the period of validity of their bid extended should likewise extend the period of validity of their tendering security, or present a new security that covers the extended period of validity. If they fail to do so, it will be assumed that they refused the request for extension.

Article 31

Modification of the bids

1. Unless otherwise provided for, competitors may modify or withdraw their bid before the end of bid submission deadline, without losing their tendering security.
2. Modification or notification on bid withdrawal will take effect if received by SAMES before the bid submission deadline expires.

Article 32

Closure of the notice or invitation and respective effects

1. Once the deadline for bid submission has expired, at the established hour, SAMES should declare that the period is closed and have a deed drawn up to record this act.
2. Any bid received after the established deadline has expired shall be returned to its sender unopened.

**SECTION FOUR
TENDERING SECURITY**

Article 33

Tendering security

1. Each competitor should lodge a security to confirm the validity of his bid, for the period laid down in the tender papers.
2. This security may be required up to a maximum 10 percent of the bid value, starting on the date of bid submission.
3. The period of validity of the tendering security should be that which has been requested for evaluating the bids and perform a number of other indispensable acts until the contract is awarded.
4. This security should be immediately returned to those competitors who are not awarded the contract.
5. SAMES should retain the tendering security of the competitor whom they intend to award the contract, until it is replaced by a performance guarantee.
6. SAMES may convert the tendering security into a performance guarantee, in case the winning bidder does not lodge the latter within the established deadline, notwithstanding his obligation to pay the difference between both securities.

Article 34

Forms of tendering security

The tendering security may be requested in the form of letters of credit or guarantees issued by a fit bank or financial institution or insurance company, in accordance with the following rules:

- a) The request should be made to all competitors on equal foot;
- b) Tender papers should stipulate the conditions concerning the issuer or guarantor, as well as the terms and form of the security, in order for it to become acceptable;
- c) Securities must include the clause of irrevocability;
- d) In case the security and the issuer meet the requirements laid down in the tender papers, the said security cannot be rejected on grounds that it was issued by a natural person or a legal person based outside the Country.

Article 35

Confirmation of the security issuer

1. Competitors have the right to request in writing that SAMES confirm the acceptability of a security issuer or a guarantor and to receive a response to such request also in writing within the shortest delay possible.

2. This confirmation of acceptability does not prevent SAMES from rejecting the security on grounds that the issuer or the guarantor, whichever is applicable, became unsolvable or without credit.

Article 36

Loss of tendering security

1. Competitors shall lose their right to claim back their tendering security if their conduct is harmful to SAMES, namely when they:
 - a) Withdraw or modify their bid during the period of validity of the said bid, of after having been awarded the contract;
 - b) Do not pay the performance guarantee in full, as laid down in the tender papers;
 - c) Do not comply with any other condition that must be met prior to contract signature, as specified in the tender papers;
 - d) Do not sign the contract on the date established by SAMES, without justification.
2. The loss of the deposited security and its causes shall be timely notified in writing to the competitor.

Article 37

Return of tendering security

1. The tendering security should be promptly returned when the reason for its deposit has ceased to exist.
2. SAMES should timely return the security paper, after one of the following events has occurred:
 - a) End of tendering security;
 - b) End of supply procedures, without any supply contract entering into force to the benefit of the competitor;
 - c) Withdrawal of the bid prior to the deadline for bid submission, unless the tender papers establish that such withdrawal is not permitted.

Section V

Commission for the Opening of Envelopes

Article 37-A

The Appointment

1. The Opening Committee, hereinafter called CAI, is appointed by the Executive Director of SAMES before the start of the pre-qualification or tender procedures, for a period of one year, without the possibility of renewal.
2. CAI must be composed of at least three SAMES employees, one of whom is appointed its chairperson.

Article 37-B

Public Act of Opening the Envelopes

1. On the day set in the pre-qualification documents or in the tender documents, in a public act, CAI will open the envelopes.
2. Any interested parties may attend the public act, without the intervention of those present being allowed.
3. In the pre-qualification procedures, the act begins with the reading of the identification of procedure, proceeding to the opening of the envelopes and, immediately afterwards, the list of competitors is made, in sight of all those present, taking a copy of this list in a document that must be signed by two witnesses chosen from among those present in the public act, preferably from among the competitors, and by the members of the CAI present.

4. In a public tender, the act begins with the reading of the identification of procedure, followed by the opening of the envelopes and, immediately thereafter, the list of competitors is made, with the prices offered, which is written in front of all present and read aloud, taking a copy of this list in a document that must be signed by two witnesses chosen from among those present in the public act, preferably from among the competitors, and by the members of the CAI present.
5. In the pre-qualification or bidding procedures, right after the public act, CAI gathers all documents, delivering them to the Standing Committee for Evaluation of Bids, or keeping them in a safe place until they are delivered to the said Committee.
6. CAI shall deliver to the Standing Committee on the Evaluation of Proposals, all documents, at the latest, on the day following the opening.

SECTION FIVE STANDING COMMITTEE ON BID EVALUATION

Article 38 Appointment and creation

1. The Standing Committee on the Evaluation of Proposals, hereinafter called CPAP, shall be appointed by the Minister of Health, upon SAMES' Executive Director's proposal, for a period of 12 months, and shall consist of three or five full members and three alternates, one of whom shall be appointed Chairman and one of his/her alternates, in the event of absence and impediment.
2. The members of CPAP are designated from among SAMES employees, and include at least two employees of the Ministry of Health's central services, one permanent and one substitute, with knowledge in the pharmaceutical area and/or medical-hospital equipment.

Article 39 CPAP powers

CPAP shall have the following powers:

- a) Open the wrappers containing the bids submitted by competitors in all supply procedures;
- b) Admit or reject the competitors, on proper grounds, based on the requirements of the pre-qualification papers or the tender papers, whichever applicable;
- c) Decide on the pre-qualification of competitors in procedures of this nature, based on the requirements of the pre-qualification papers;
- d) Evaluate the bids and rank competitors, according to the selection criteria defined in the tender papers;
- e) Evaluate, select and rank competitors;
- f) Propose the competitor whom the contract should be awarded.

Article 40 Functioning of CPAP

1. For each supply procedure, CPAP shall be performing its functions as from the moment when the bids submitted by the competitors are opened.
2. CPAP should draw up minutes of the meetings and attend to current business, among which should be included the causes for excluding competitors.

Article 41
Opening of the wrappers

[Repealed]

Article 42
Admission and exclusion of competitors

1. CPAP shall hold a private session for appraising the tender bids.
2. After appraising them, CPAP shall decide as to the admission or exclusion of competitors, as well as their ranking.
3. Criteria to be adopted by CPAP shall be made public in advance, on the prequalification papers or the tender papers, whichever applicable.

Article 43
List of admission and exclusion

Before the end of the private session held by CPAP for admitting and excluding competitors, a list of admitted and excluded competitors shall be drawn up and certified by all members present giving the reasons and grounds for their decision, although briefly.

Article 44
Bid evaluation

1. In tendering procedures CPAP shall evaluate the tender bids in a private session.
2. Bids shall be excluded if they:
 - a) Are submitted by the same competitor;
 - b) Fail to comply with the requirements laid down in the tender papers.
3. In tendering procedures the chairman of CPAP subsequently announces the total price of each admitted bid and its key attributes.

SECTION SIX
EVALUATION, SELECTION AND RANKING OF
COMPETITORS

Article 45
Evaluation in pre-qualification procedures

1. CPAP, based on the requirements established in the pre-qualification papers, shall decide which competitors are pre-qualified.
2. The list of pre-qualified competitors must be drawn up and the minutes of the procedure with the respective individual foundations signed by the members of the CPAP who participated in the procedure, valid as a final report, to be delivered to the Executive Board within a maximum period of three days, counting from the date of conclusion of the evaluation, for ratification.
3. In case the list of pre-qualified members is approved, it is sent to the Procurement Service for publication. If not, it is returned, with due justification, to the CPAP, for re-evaluation.
4. The list referred to in the previous number is published under the terms established in article 49 of the present legal diploma.

Article 46

Evaluation and selection in tendering procedures

1. CPAP shall evaluate and rank the competitors according to the tender paper requirements, inasmuch as possible beginning by evaluating the competitors in the following order:
 - a) Professional background;
 - b) Technical skills and experience;
 - c) Financial capacity.
2. CPAP shall then evaluate the bids, in the following order:
 - a) Delivery deadline;
 - b) The quality of medicines, medical supplies and medical-hospital equipment;
 - c) The specifications and quality guarantees of medicines, medical supplies and medical-hospital equipment;
 - d) Other requirements of the tender papers;
 - e) Total price and terms of payment.
3. CPAP shall then apply the percent values of the selection factors laid down in the tender papers, ranking the competitors.
4. Should there be a tie the contract shall always be awarded to the lowest or the most economically advantageous bid, if the competitor has been approved in the technical evaluation.
5. A mandatory list containing the final rank shall be drawn up and the minutes of the meeting drafted, giving the grounds for the rank of each competitor. Both shall be certified by the CPAP members present and have the value of a final report.
6. The CPAP shall complete the evaluation of proposals and present the report to the Executive Board within fifteen days from the date of opening of the proposals.

Article 47

Examination by the SAMES Board of Directors

1. The report of the current procedure shall be delivered to the Chairperson of the Executive Board within three days after its conclusion and the Executive Board shall decide within a maximum of five days.
2. If the decision of the CPAP is ratified, the recommendation must be sent to the Procurement Service to process the contract.
3. If the decision of CPAP is rejected, the Executive Board must state the reasons for its decision and refer it to the CPAP for further analysis.
4. In the cases foreseen in the previous number, the CPAP can propose the second qualified competitor and so on successively or, propose to the Board the realization of a new procedure.

Article 48

Rejection of all bids

1. SAMES has the right, at any moment before awarding the contract, to reject all submitted bids. This decision must be reported to all competitors, but does not have to be justified.
2. In case SAMES allege this right, they shall not be liable to the competitors.

Article 49
Decision made public

1. The notice with the decision taken by SAMES, referring to all pre-qualified competitors or the intention to award the contract to one competitor, shall be made public in the usual SAMES locations, briefly explaining the reasons for the choice.
2. This notice should remain visible to the public for at least five days in prequalification procedures and for at least fourteen working days after its publication in tendering procedures.

Article 50
Abandoned bid

1. When the competitor ranked in the first place after selection, following his proper notification, fails to sign the contract or lodge the contract performance guarantee on the scheduled date, his bid should be considered abandoned, together with a declaration ruling the loss of his tendering security to the benefit of SAMES.
2. When faced with a situation of bid abandonment, SAMES may choose from one of the following alternative options:
 - a) Use their right to reject all bids;
 - b) Select another valid bid, according to the order of results established during the evaluation stage, and repeat all procedures of acceptance and notification for subsequent award of the contract.

SECTION SEVEN
CLAIMS AND APPEALS

Article 51
Right to claim

1. Competitors who deem to have suffered damage in the course of a supply procedure by tendering, pre-qualification and partial invitation, shall have the right to file a claim to CPAP on the following grounds:
 - a) Non compliance with the rules set forth in this decree-law;
 - b) Non compliance with the terms and conditions laid down in the prequalification or tender papers;
 - c) Non compliance with a decision adopted by CPAP that may have infringed the legal rules in force.
2. Claims should be filed within five days after the decision is made public.

Article 52
Stages of claim appraisal

1. CPAP must receive submitted complaints and decide about their admission, within a maximum period of five days, and submit them to the Executive Director or to entity whereby the power is delegated, to authorize the procurement procedure in complaint.
2. The only grounds for refusing admissibility are that the claim has been submitted after expiry of the deadline.
3. Once the claim has been admitted, suspension of the procedure shall be decided within two days.
4. The Executive Director of SAMES or the one to whom the power to authorize the procurement procedure in complaint is delegated, may suspend the procedure for a period of five days, extendable for the same period, if there are reasons that justify it.

5. As long as there is no decision in transit in administrative procedures relative to the complaint or to the hierarchical appeal, the adjudication cannot be made in all the procedures.

Article 53

Decision on the filed claim

1. After analyzing the case, the Executive Director or the entity to whom the power to authorize the procurement procedure in complaint is delegated, after hearing the Executive Board of SAMES, must decide whether to accept or reject the complaint presented, within a period of five days.
2. Decision on the filed claim should consist of a document mentioning the grounds on which it was made and shall be immediately notified to all parties concerned.

Article 54

Hierarchic recourse

1. Competitors who do not accept the decision made on their claim may file a petition of hierarchic recourse to the Health Minister within five days following the date of notification of the decision on their claim.
2. Hierarchic recourse may suspend the procedure for a maximum period of five days.
3. After appraising the case, the Health Minister should decide whether to accept or reject the claim within five days.
4. The decision on the recourse should consist of a document mentioning the grounds on which it was made and should be immediately notified to the concerned parties.
5. Judicial recourse shall produce no suspensive effects.

CHAPTER FIVE

STAGES IN PROCEDURES WITHOUT COMPETITION

Article 55

Request for quotations procedure

1. In the procedures by request for quotations, the invitation, duly signed by the Executive Director of SAMES is addressed to at least three suppliers already known by SAMES or selected in advance by the pre-qualification procedure, attaching the quotation document, which must contain at least:
 - a) The list of medicines, medical supplies and medical-hospital equipment, specifying their quantity and quality;
 - b) The terms and conditions of the quality guarantee;
 - c) A summary of the main terms and general conditions governing the contract to be signed;
 - d) The deadline for submitting the quotations.
2. Once the submission deadline has expired, CPAP shall immediately evaluate and compare the quotations so as to choose the lowest bid, basing their evaluation on technical criteria specified in the quotation document.
3. The choice made in accordance with the previous number shall be submitted to the Executive Board of SAMES for ratification.
4. The choice and intention to award should be immediately notified to the participants in the request for quotations procedure, making reference to the reasons for the choice.

5. Participants in a request for quotations procedure who consider to have been harmed by the choice and intention to award have the right to submit a request for clarification to CPAP, who should respond within three days.
6. Requests for clarification shall produce no suspensive effects.
7. The participants in the procedure for requests for quotations not in conformity with the response of the CPAP may lodge a hierarchical appeal with the Executive Director of SAMES who, after hearing the Executive Board, must respond within three days.
8. The Executive Director's response constitutes the final response.

Article 56

Contract by direct agreement procedure

1. In procedures by direct adjudication, SAMES may address one or certain suppliers to meet specific supply needs.
2. After verifying the existence of special circumstances, foreseen in paragraphs 1 and 2 of Article 12, the Executive Director of SAMES submits to the Executive Board, for ratification, the list of medicines, medical supplies and medical-hospital equipment, as well as detailed information of one or more specific suppliers to be chosen.
3. After ratification by the SAMES Executive Board, the Procurement Service processes the contract with the chosen supplier.

CHAPTER SIX

SPECIAL AND FINAL PROVISIONS

Article 57

Statement of ownership

1. Any officials of SAMES or the Health Ministry in charge of participating in SAMES supply procedures and operations should present a statement of assets owned and those owned by their spouse, or the person with whom they live de facto.
2. The approved model for the assets statement is attached to this decree-law and is a full part of it.
3. The Inspector-General is the competent body for receiving the ownership statements, monitoring and keeping the respective files.

Article 58

Contracting scheme

The general norms in terms of procurement and public contracts apply in everything that does not contradict the provisions of the present document".

Article 59

Scheme governing administrative offences

Specific rules governing administrative offences under this decree-law shall be those stipulated in Decree-Law no 11/2005, of November 21, 2005, on Administrative Offences against the Legal System on Supply and the Legal System on Public Contracting, with the necessary adaptations.

Article 60

Entry into force

This decree-law shall enter into force on the day immediately after its publication.

Approved by the Council of Ministers on the 5 November 2008.

The Prime Minister

(Signature)

Kay Rala Xanana Gusmão

The Minister of Health,

(Signature)

Nelson Martins

Enacted on the 18 December 2008.

Be it published.

The President of the Republic

(Signature)

José Ramos-Horta