#### DEMOCRATIC REPUBLIC OF TIMOR-LESTE

#### GOVERNMENT

### **DECREE No. 2/2004**

OF

### AUTONOMOUS DRUG AND MEDICAL EQUIPMENT SERVICE

In February 2003, the Council of Ministers approved a policy for the creation of a public enterprise to import, store and distribute drugs and medical equipments for the development of the "Health Policy Structure of Timor-Leste," which had also been approved previously, aimed at improving and rendering more efficient the supply of drugs, medical equipments and other medical consumption goods to institutions belonging to the health system, in particular to the National Health Service.

Subsequently, Decree-Law No. 14/2003 of 24 September established the legal framework of public enterprises.

It is thus of interest to create the Autonomous Service of Drugs and Medical Equipment, which is to be a Public Enterprise.

Therefore, pursuant to Article 3 of Decree-Law No. 14/2003 of 24 September, the Government decrees the following that shall have the force of regulation:

# Article 1 (Purpose)

The present statute shall have as its aim the creation of a public enterprise to import and distribute drugs, medical products and medical equipments.

# Article 2 (Establishment and Nature)

- 1. The Autonomous Service of Drugs and Medical Equipment, hereinafter SAMES, is hereby created and it shall have the character of a public enterprise.
- 2. SAMES shall be endowed with a legal personality with administrative, financial and patrimonial autonomy.
- 3. The legal capacity of SAMES shall comprise all rights and duties necessary for the attainment of its purpose as defined in the Statutes.
- 4. The statutes of SAMES, annexed to the present statute and that form an integral part therein, are hereby approved and the respective publication shall be sufficient for registration.

### Article 3 (Regime)

SAMES shall be governed by the present statute and its respective statutes, by Decree-Law No. 14/2003, by the other rules applicable to the business sector of the State and, subsidiarily, by the rules of Private Law.

## Article 4 (Superintendence)

- 1. SAMES shall exercise its activity under the supervision of the Health Minister upon whom it shall be incumbent:
  - (a) To define the guiding lines for the preparation of the activity plans and budgets;
  - (b) To require all necessary information so as to follow SAMES activities, and to establish audits and inspections of its functioning;
  - (c) To define the parameters for any collective negotiation that takes place;
  - (d) To approve the rules of procedure;
  - (e) To authorise the acquisition or alienation of movable and immovable properties subject to registration and financial participations when the respective global appropriations are not provided for in the approved budgets;
  - (f) To approve price tables and marketing margins;
  - (g) To determine the possibility of selling goods to private institutions for profitable purposes.
- 2. In addition to other control powers established by law, activity plans and annual and multiannual budgets, as well as the annual report on management and the other accountability documents shall be subject to the approval of the Minister of Health and the Minister of Planning and Finance.

# Article 5 (Principles of Management)

- 1. SAMES shall conduct its management in accordance with the economic and health policies of the State, aiming at promoting development and ensuring economic viability and financial balance.
- 2. SAMES shall conduct its management in accordance with the following principles and objectives, among others:
  - (a) Purchase of drugs, medical products and medical equipment so as to provide the institutions of the health system with a better cost-quality relation, in accordance with the aims established in contract-programmes;
  - (b) Stipulate prices that allow the total costs of exploitation to be covered and that ensure adequate levels of self-financing and return on capital invested within a reasonable time frame, without compounding inflationist trends and subordinating such actions to a national policy of salaries and prices;
  - (c) Obtain appropriate rates of return on capital invested in new investments while considering the cost-benefit analysis from an economic and social standpoint;

- (d) Minimise costs through a better utilisation of available resources aimed at obtaining maximum efficacy in its contribution towards economic and social development;
- (e) Have a wage policy that is suitable for the national labour market by promoting collective labour contracts for medium and short-term periods so as to create social harmony and allow salary growth on the basis of productivity.
- (f) Select and manage professionals on the bases of qualification and merit.

### Article 6 (Registered Capital)

- 1. The registered capital shall be of \$1,635,000 dollars and it shall be fully underwritten and realised by the State.
- 2. The goods, rights and duties transferred to SAMES in accordance with Article 9 shall be included in the capital, as reserves, for their book value.
- 3. The Ministry of Planning and Finance shall valuate the goods referred to in item 2 above, from the date of the entry into force of the present statute, and the value of the registered capital shall change in accordance with the value of the valuation, without any other formality other than the alteration record.

# Article 7 (Exemptions)

SAMES shall be exempt from duties, taxes, costs and emoluments on proceedings of any nature, notarial acts and other cases in which it is involved.

## Article 8 (First Board of Directors)

Within a maximum period of 90 days, to be counted from the date of its nomination, the first board of directors shall:

- (a) Register SAMES in the Commercial Registry;
- (b) Submit the rules of procedure to the Minister of Health;
- (c) Submit the 2004-2005 Activities and Financial Plan to the Minister of Health.

## Article 9 (Succession)

- 1. SAMES shall succeed to all rights and duties of the Central Pharmacy, now defunct.
- 2. Movable and immovable properties of the State, belonging to that institution, shall be SAMES' own property.
- 3. The employees of the above-mentioned institution shall automatically become a part of SAMES and shall maintain the same contractual situation.
- 4. Functions of persons in charge of the Central Pharmacy shall cease on the date in which the Board of Directors of SAMES takes office.

### Article 10 (Transitional Provisions)

- 1. Drugs, medical products and medical equipments in stock at the Central Pharmacy on the date of the entry into force of the present statute as well as the drugs SAMES shall acquire in subsequent years with funds from the General Budget of the State, shall be kept as property of the State, and SAMES shall be bound to store and distribute them through the National Health Services institutions.
- 2. For this purpose and until such a time as the registered capital is reinforced, the operational costs of the SAMES shall be paid by means of transfers made through the General Budget of the State.

### Article 11 (Entry into Force)

The present statute shall enter into force on the following day after its publication.

Approved by the Council of Ministers on 18 March 2004.

To be published.

The Prime Minister

[Signed] (Mari Bim Amude Alkatiri)

The Minister of Health

[Signed] (Rui Maria de Araújo)

### ANNEX (Referred to in Article 2.4)

### STATUTES OF THE AUTONOMOUS DRUG AND MEDICAL EQUIPMENT SERVICE

### CHAPTER I (General Provisions)

## Article 1 (Structure and Designation)

The Autonomous Drug and Medical Equipment Service, hereinafter SAMES, shall be a public enterprise.

## Article 2 (Headquarters and Location)

- 1. SAMES shall have its headquarters in Campo Alor, in Dili, and shall carry out its activities nationwide.
- 2. SAMES may have delegations, agencies or any other type of representation in the national territory as defined by its rules of procedure.

## Article 3 (Purpose)

- 1. SAMES shall have as its aim to ensure the supply of drugs, medical consumption goods and medical equipments to the health system and, in particular, to the National Health Service, in accordance with the provisions of the law and of these Statutes, and shall:
  - (a) Acquire, especially by import, drugs, goods for medical consumption and medical equipments necessary for the functioning of the health system;
  - (b) Store such goods and manage the respective stocks;
  - (c) Distribute such goods to requesting National Health Services institutions as well as to other public institutions, upon payment;
  - (d) Sell the goods to private, profitable or non-profitable institutions integrated into the health system, upon prior payment.
- 2. SAMES shall collaborate with the remaining institutions of the Ministry of Health and, namely, with regulatory entities of the pharmaceutical domain, in establishing a policy for the domain of drugs, and namely in establishing:
  - (a) A system for drug quality control;
  - (b) A registry of authorised drugs to be introduced into the market;
  - (c) A National List of Essential Drugs;
  - (d) A Supplementary List of Drugs;
  - (e) A List of Essential Medical Products and Equipments.

### Article 4 (Registered Capital)

The registered capital shall be of \$1, 635,000 dollars, which shall be fully underwritten and realised by the State.

## Article 5 (Regime)

SAMES shall be governed by the present statutes, by the rules applicable to the business sector of the State and, subsidiarily, by the rules of Private Law.

### Article 6 (Autonomy)

SAMES shall exercise its activity autonomously within the framework of the law, without prejudice to the guiding principles on health policy established by the Government and to supervisory powers provided for by law.

### Article 7 (The Rule of Specification)

The legal capacity of SAMES shall comprise the necessary rights and duties for the pursuit of its purpose, and it may not exercise activities, use their powers, or dedicate its resources for different purposes.

## CHAPTER II Establishment, Competency and Functioning of Organs

## Article 8 (Organs)

SAMES shall be comprised of the following organs:

- (a) The Board of Directors;
- (b) The Fiscal Council.

### SECTION I Board of Directors

### Article 9 (Composition)

1. The Board of Directors shall be composed by a chairperson, appointed by the Council of Ministers, and six members, appointed by the Minister of Health, four of whom shall be executive directors, one shall represent the Ministry of Planning and Finance and one shall represent, by means of elections, SAMES employees.

- 2. Members of the Board of Directors shall be appointed from among persons selected on the basis of recognised integrity, independence, as well as technical and professional competencies.
- 3. Terms in office shall last for four years and they shall be renewable for equal periods.

## Article 10 (Competence)

The Board of Directors shall be the management organ of the company, and it shall be particularly incumbent upon it to:

- (a) Provide SAMES with direction and senior management and exercise all necessary competencies to the achievement of its aim;
- (b) Approve SAMES' rules of procedure including the elements set out in Article 8.2 of Decree-Law No. 14/2003 of 24 September;
- (c) Approve the management policy of the company;
- (d) Examine and vote on annual and multiannual budgets as well as on activities plans, within the legally required timeframes;
- (e) Examine and vote on accountability documents and on application proposals regarding the results of the economic exercise of the previous year within the legally required timeframes;
- (f) Collect revenue, encourage coercive collection of debts, and authorise the realisation of expenses;
- (g) Administer SAMES' property and approve the acquisition and disposal of movable and immovable goods subject to registration and financial participation when such actions are provided for in the approved annual budgets;
- (h) Manage human resources and exercise disciplinary power;
- (i) Conclude collective labour conventions;
- (j) Submit to the supervisory Minister for approval acts and documents, which must be so submitted, in accordance with the law and the present Statutes.

### Article 11 (Functioning)

- 1. The Board of Directors shall meet ordinarily once a week and extraordinarily whenever convened by its chairperson, or, upon the request of two of its members or upon the request of the Fiscal Council.
- 2. The Board of Directors may only make decisions when the majority of its members are present; it shall decide by majority, and the chairperson shall have the casting vote. Minutes shall be taken of the meetings.

# Article 12 (Delegation of Competencies)

The Board of Directors may delegate competencies conferred upon it to one or more of its members.

### Article 13 (Legal Obligation)

SAMES shall be bound by:

- (a) The joint signature of the chairperson, or his/her substitute, and of another member;
- (b) The signature of one of the members who, for that purpose and as recorded in the minutes, has received delegation for such powers;
- (c) The signature of whoever is duly authorised for such purpose in accordance with Article 14.

## Article 14 (Chairperson)

- 1. It shall be incumbent upon the Chairperson of the Board of Directors to coordinate and guide the activities of the Board, and in particular:
  - (a) To convene and preside over the meetings of the Board of Directors, to coordinate its activities and those of the executive directors and to ensure the implementation of his/her decisions;
  - (b) To co-ordinate the actions of all the services of SAMES;
  - (c) To represent SAMES, in a Court of law or otherwise, namely before the supervisory Minister, when other mandated representatives have not been appointed.
- 2. Whenever urgent circumstances so require and it is not possible to convene the Board of Directors, the chairperson may carry out any acts of the Board of Directors, which must be ratified during the first subsequent meeting.
- 3. The chairperson of the Board of Directors shall be substituted during his/her absences and inability to act by the member appointed by him/her.

## Article 15 (Status of Members)

- 1. The members of the Board of Directors shall be subject to the statute of public managers on everything that does not originate from the present statutes.
- 2. The chairperson and the executive directors shall perform their functions on a full-time basis and shall earn salaries as established by a joint administrative instruction of the Minister of Planning and Finance, the Minister of Health, and the Minister of State Administration.
- 3. The remaining two members shall be paid through attendance coupons of a value established by a joint administrative instruction of the Ministers referred to in item 2 above.
- 4. General social security arrangements shall be applicable to members of the Board of Directors who discharge their functions on a full-time basis except when they belong to the cadres of the civil service, in which case their own rules regarding their place of origin shall be applicable, in accordance with the provisions established in the respective law.

- 5. Members of the Board of Directors, who carry out their functions on a full-time basis, may not, during their term of office, exercise any other professional function or activity, except teaching on a part-time basis.
- 6. Members of the Board of Directors shall be subject to incompatibilities and impediments from holders of high public offices.

### Article 16 (Cessation of Functions)

- 1. A Member of the Board of Directors shall cease his/her functions:
  - (a) At the end of his/her respective term in office;
  - (b) Due to permanent disability or supervening incompatibility;
  - (c) By resignation;
  - (d) By dismissal decided by the entity that appointed him/her, after consultation with the proponent entity, in cases of serious proven offence committed during the exercise of his/her functions;
  - (e) Following conviction for having committed a felony.
- 2. In case of individual cessation of the term in office, the new member shall always be appointed for a period of four years.

### Article 17 (Dissolution)

The Board of Directors may be dissolved by a decision of the Council of Ministers, upon a proposal of the Minister of Health and in case of serious errors in its functioning and of considerably high expenses over budgeted allocations, without proper justification.

### SECTION II Fiscal Council

### Article 18 (Composition)

- 1. The Fiscal Council shall be composed of three members appointed by the Minister of Planning and Finance, following consultation with the Minister of Health, one of whom shall preside and another shall be a statutory auditor or an accountant.
- 2. Terms in office shall last for four years.

## Article 19 (Competence)

- 1. The Fiscal Council is the supervisory organ for the management of SAMES, and it shall be particularly incumbent upon it:
  - (a) To verify the legality of financial deeds of the Board of Directors, its compliance with statutes and other applicable rules;
  - (b) To monitor the execution of the activity and financial plans;

- (c) To examine the accounting of SAMES and the budgetary execution on a periodical basis;
- (d) To pronounce on the criteria for the valuation of goods, for amortisation and reintegration of capital, for the creation of provisions and reserves, and for determining financial results;
- (e) To verify the accuracy of the balance sheet, of the profit and loss account, of the trading account and the remaining elements, to issue an opinion on such matters as well as on the annual report of the Board of Directors;
- (f) To pronounce on the performance of, and on the financial management of, the company regarding the achievement of results and projected benefits;
- (g) To give an opinion on the acquisition, disposal or price-raising of immovable goods and motor vehicles;
- (h) To inform the supervisor of irregularities verified in the management of SAMES.
- 2. For the exercise of its competencies the Fiscal Council may:
  - (a) Request information and clarifications from the Board of Directors regarding SAMES' activities;
  - (b) Propose external audits to the Board of Directors;
  - (c) Participate in Board of Directors meetings, through the chairperson or another member, without the right to vote.

## Article 20 (Functioning)

The Fiscal Council shall meet ordinarily once a month and extraordinarily whenever convened by the chairperson, either on his/her initiative or upon request from another member.

### **CHAPTER III**

### (Economic and Financial Management and Human Resources)

### Article 21 (Property, Economic and Financial Management)

The property, economic and financial management of SAMES shall be exercised in accordance with the Articles that follow and in compliance with the rules set out in Chapter III of Decree-Law No. 14/2003 of 24 September.

## Article 22 (Property)

The property of SAMES shall consist of all assets, rights and duties received, acquired or incurred in the exercise of its activity, and it shall respond exclusively for incurred debts.

### Article 23 (Revenue)

The following shall constitute revenue of SAMES:

- (a) Amounts arising from the sale of goods and provision of services in accordance with the law as well as with contracts and price tables;
- (b) Income from own goods;
- (c) Profits from the disposal of own goods and their entitlements;
- (d) Allocations, shares and subsidies from the State or other entities;
- (e) Donations, inheritances or legacies;
- (f) Any other income or values arising from its activity or that belong to it, by law or by contract.

## Article 24 (Instruments of Management)

The property and financial management of SAMES shall be governed by the following instruments of forward management:

- (a) Annual programme, which includes the activity plan, the financial budget or treasury, the trading budget and the investment budget;
- (b) Medium-term programme, for a minimum period of three years, which shall include the documents referred to in paragraph (a) above appropriate to the period.

## Article 25 (Dates of Submission)

- 1. By 15 October of each year, the Board of Directors of SAMES shall forward to the Minister of Health the basic elements of the plans of production and investment for the following year.
- 2. By 28 February of each year, the Board of Directors of SAMES shall submit the trading budget and investment projects to the Minister of Health, who, following consideration and endorsement, shall propose its approval to the Minister of Planning and Finance in accordance with Article 22.3 of Decree-Law No. 14/2003.

## Article 26 (Accountability Documents)

- 1. During the month of October of each year and with reference to 30 June, SAMES shall prepare and forward to the Minister of Health the following documents along with the opinion of the Fiscal Council:
  - (a) The Board of Directors Report describing how the desired objectives were achieved;
  - (b) The balance sheet and the position statement;
  - (c) A list of stakes in the capital of companies and of financing in the medium and long term;
  - (d) The statement of sources and use of funds.

2. The Minister of Health shall examine and submit the above-mentioned documents for approval by the Minister of Planning and Finance, in accordance with the provisions of Article 26 of the Decree-Law No. 14/2003.

### Article 27 (Human Resources)

- 1. SAMES' employees shall be subject to individual employment contracts and SAMES shall encourage the signing of collective labour conventions.
- 2. Mobility of SAMES' employees to other entities and from other entities to SAMES shall take place in accordance with the provisions and manner provided for by law.
- 3. Public Administration employees and agents as well as public enterprise employees may exercise functions in SAMES, on the basis of secondment, requisition or temporary assignment.
- 4. The functions carried out in accordance with the items above shall be accomplished with a guarantee of the place of origin and without prejudice to any rights, and such functions shall be considered as having been exercised at the place of origin, for the purposes of counting service time.