

OFFICIAL GAZETTE

[Coat of Arms]

OFFICIAL GAZETTE OF THE REPUBLIC OF MOZAMBIQUE

NATIONAL PRESS OF MOZAMBIQUE, E. P.

NOTICE

The matter to be published in the "Official Gazette" must be sent in duly certified copies, one for each subject, containing, in addition to the information required for this purpose, the following signed and authenticated endorsement: For publication in the "Official Gazette".

SUMMARY

Ministry of the Interior:

Correction:

Concerning Decree no. 89/2023 of 29 December.

Ministry of Industry and Commerce:

Ministerial Diploma no. 23/2024:

Creates the CAP Steering Committee and approves its Rules of Procedure.

Interministerial Commission for Public Administration Reform:

Resolution no. 1/2024:

Approves the Organic Statute of the Central de Medicamentos e Artigos Médicos, Instituto Público, abbreviated as CMAM, IP.

MINISTRY OF THE INTERIOR

Correction

Having noticed some errors in the publication of Decree no. 89/2023, of 29 December, approving the Organic Statute of the National Migration Service, published in the *Official Gazette* no. 250, of 29 December 2023, Series I, 15th Supplement, the following is corrected:

In Article 23 no.2, "The Directorate for Migration Inspection" should read: "The Directorate for Doctrine and Ethics".

In Article 50 no.1, paragraph *a)*, *c)* and *d)* should be deleted.

Article 52, in terms of sequence, should read article 51 and article 51, should read article 52.

In article 51 (Provincial Planning and Statistics Office), no. 1, paragraph *b)*, reads: "to analyse the degree of execution of the plans and programmes carried by the Provincial Directorate", must be read: "prepare accountability reports and analyse the degree of execution of the plans and programmes of the Provincial Directorate".

In Article 55, a paragraph 2 should be inserted with the wording that appears loose, before Article 56, with the following

wording "The Office of the Provincial Director shall be headed by a Chief with the rank of Migration Superintendent, appointed by the Minister who oversees the area of Migration, after hearing the Director General."

MINISTRY OF INDUSTRY AND COMMERCE

Ministerial Diploma no. 23/2024

of 26 March

In view of the need to ensure the direct and active involvement of all public and private entities with responsibilities in matters of industry and commerce in the implementation of the Conformity Assessment Programme (CAP) and pursuant to the provisions of article 2 of Decree no. 8/2022, of 14 March, the Minister of Industry and Commerce determines:

Article 1. The CAP Steering Committee is hereby created, a collegiate consultative body, without legal personality, subordinate to the Minister who oversees the area of industry and commerce, whose purpose is to supervise and monitor the CAP implementation.

Art. 2. The Rules of Procedure of the CAP Steering Committee attached to this Ministerial Diploma, of which it forms an integral part, are hereby approved.

Art. 3 This Ministerial Diploma shall enter into force on the date of its publication.

Ministry of Industry and Commerce, in Maputo, 22 February 2024. - The Minister of Industry and Commerce, *Silvino Augusto José Moreno*.

Rules of Procedure of the Conformity Assessment Programme Steering Committee

CHAPTER I General Provisions

Article 1 (Object)

This Regulation establishes the basic operating principles of the Conformity Assessment Programme (CAP) Steering Committee.

Article 2 (Nature and Head Office)

1. The CAP Steering Committee is a collegiate consultative body, without legal personality, subordinate to the Minister who oversees the area of Industry and Commerce, which

ensures the follow-up and monitoring of CAP implementation processes.

2. The CAP Steering Committee is headed by the Minister responsible for Industry and Commerce.

3. The CAP Steering Committee is based at the Instituto Nacional para Normalização e Qualidade-IP (INNOQ, IP) in Maputo.

Article 3

(Scope)

The provisions of this Regulation shall apply to the members of the CAP Steering Committee.

CHAPTER II

Composition and operation of the Steering Committee

Article 4

(Composition)

1. The CAP Steering Committee is made up as follows:
 - a) two representatives from industry and commerce;
 - b) a representative from the agricultural sector;
 - c) a representative from the environmental sector;
 - d) a representative from the transport and communications sector;
 - e) a representative from the health sector;
 - f) a representative from the fisheries sector;
 - g) a representative from the mineral resources and energy sector;
 - h) a representative from the public works, housing and water resources sector;
 - i) a representative of the Tax Authority;
 - j) a CTA representative;
 - k) a representative of the Association of Small and Medium-sized Enterprises; and
 - l) a representative from Procurers.

2. Although the tripartite nature of the Steering Committee must be maintained (government, civil society and the private sector), the Steering Committee can at any time agree to change, add or reduce the number of members.

3. Without prejudice to paragraph 2 of this Article, the Chairman of the Committee shall have the right of veto to safeguard the public interest.

4. The Steering Committee is supported in its activities by a secretariat.

Article 5

(Guests)

They are invited to CAP Steering Committee meetings, without the right to vote, at the express invitation of the Steering Committee Chairman:

- a) the Head of the Secretariat of the CAP Steering Committee; and
- b) entities and other personalities of recognised technical competence, experience and professional standing, from sectors of activity with responsibility in matters of industry and commerce.

Article 6

(Appointment and mandate)

1. The members of the CAP Steering Committee are appointed by the managing bodies of the areas referred to in Article 4(1) and confirmed by the Minister responsible for Industry and Commerce.

2. The members of the CAP Steering Committee are appointed for an initial term of two (2) years and may be reappointed for a further term of equal duration.

Article 7

(Loss of mandate)

1. Members of the Steering Committee who miss two consecutive meetings or four interpolated meetings without written justification shall lose their mandate.

2. Likewise, those who commit acts incompatible with the law or who are sentenced to a longer prison term lose their mandate.

Article 8

(Duties of Members)

The duties of Steering Committee members are:

- a) prioritise participation in the Steering Committee's sessions, on the days and at the times stipulated for this purpose;
- b) attend the sessions of the steering Committee and other meetings to which they have been convened;
- c) record in writing the opinions requested of them and submit them within the stipulated time; and
- d) participate in the discussions and deliberations of the sessions.

Article 9

(Members' rights)

The rights of steering Committee members are:

- a) attend all sessions of the Steering Committee and other meetings to which they have been convened;
- b) be informed of all the activities and deliberations of the CAP;
- c) request the convening of Steering Committee sessions;
- d) propose the inclusion of items in the draft agenda for the Steering Committee meeting;
- e) propose amendments to the Steering Committee Rules of Procedure;
- f) exercise their right to vote; and
- g) receive the amount corresponding to the attendance ticket for the sessions they have attended.

Article 10

(Functions of the Steering Committee)

The Steering Committee has the following functions:

- a) provide thought leadership and guidance for CAP operations;
- b) ensure that the programme is linked to other existing policies and programmes;
- c) supervise the process of programme implementation;
- d) inform the decision-making process; and
- e) keep your peers informed about the dynamics of the programme.

Article 11

(Chairmanship of the Steering Committee)

The Minister responsible for Industry and Commerce chairs the CAP Steering Committee, with the prerogative to appoint his replacement, who must come from institutions representing the government.

Article 12

(Duties of the Chairman of the Steering Committee)

The Chairman of the Steering Committee has the following duties:

- a) chair the Committee's sessions;
- b) authorise proposed dates and venues for the sessions, once they have been appointed; and
- c) convene the members of the Committee to the meetings.

Article 13

(Steering Committee Sessions)

1. The Steering Committee meets in sessions chaired by its Chairman.

2. If the Chairman of the Steering Committee is absent or unable to attend, a substitute shall be appointed from among the members of the Steering Committee representing the Government to lead the meeting and coordinate the work of the Steering Committee.

3. The Steering Committee meets in ordinary sessions every three months and in extraordinary sessions whenever necessary, at the initiative of its Chairman or at the request of its members.

4. Ordinary sessions are held at the appropriate venue and are convened in writing by the respective Chairperson at least seven days in advance.

5. Extraordinary sessions are organised at the initiative of the Chairperson or at the request of one third of the members, with at least two days' notice.

6. Without prejudice to the provisions of paragraph 4 of this article, the sessions of the Steering Committee may, if necessary, be held virtually/remotely or within a hybrid framework using electronic platforms, in particular video conferences.

7. Notices of meetings must contain the date, time and agenda of the meeting, as well as the relevant supporting documentation.

Article 14

(Quorum and deliberations)

1. The sessions of the Steering Committee begin with the approval of the agenda for the day and the presentation of the summary of the previous session.

2. The Secretariat shall ensure that the summary is read out and that a quorum is confirmed, requiring the presence of at least fifty-eight per cent of its members, including at least one representative from each of the member parties.

3. The absence of a quorum shall result in the adjournment of the Committee meeting.

4. The resolutions of the Steering Committee are taken by a simple majority vote of the members present and are binding. They are valid if more than half of its members vote in favour, with the Chairman having the casting vote in the event of a tie.

5. The members of the Committee are bound by the law and the by the deliberations they produce.

Article 15

(Minutes)

1. The minutes drawn up for each session of the Steering Committee shall include the names of all members present and absent, the agenda and an indication of the decisions taken.

2. The minutes shall be signed by all the members of the Steering Committee present at the respective sessions.

3. The minutes of the Steering Committee meetings shall be validated by the signature of the Chairman of the Steering Committee.

4. The Director-General of INNOQ, IP, is the depositary of the minutes of the meetings of the CAP Steering Committee.

Article 16

(Attendance Ticket)

1. Members of the Steering Committee and the secretariat are entitled to one attendance ticket for each working session they have attended.

2. The amount of the attendance fee is set by resolution of the Steering Committee.

3. Unjustified absences from a session of the Steering Committee do not give rise to an attendance ticket.

CHAPTER III

Steering Committee Secretariat

Article 17

(Structure of the Secretariat)

The Secretariat is the body that assists the Steering Committee, materialising the Committee's plan of activities and deliberations.

Article 18

(Composition of the Secretariat)

1. The Committee Secretariat is made up of four members appointed by the Chairman of the Committee, two of whom must be technical staff from INNOQ, IP, and two from the Ministries represented on the Committee.

2. The Secretariat of the Steering Committee shall be headed by the Director General of INNOQ, with the most senior technician among those referred to in paragraph 1 of this Article as his deputy.

Article 19

(Duties of the Secretariat)

The functions of the Secretariat are:

- a) drawing up notices of meetings and, with the Chairman's consent, sending them to members and/or those invited to sessions;
- b) draw up separate written minutes, summaries and recommendations and send them to the members of the Steering Committee ;
- c) support the Steering Committee in programming activities;
- d) organising and distributing documentation to support the work of the Steering Committee, before, during and after the sessions; and
- e) ensuring logistical and bureaucratic support for the sessions, including the effective implementation of the decisions or guidelines of the Steering Committee.

CHAPTER IV
Final Provisions

Article 20
Omissions and doubts

Any omissions or doubts that may arise from the application of the provisions of these Regulations will be resolved by the Order of the Minister who oversees the area of Industry and Commerce.

**PUBLIC ADMINISTRATION REFORM
INTERMINISTERIAL COMMISSION**

**Resolution no. 1/2024 of
26 March**

There is a need to approve the Organic Statute of the Central de Medicamentos e Artigos Médicos, Instituto Público, created by Decree no. 13/75, of 6 September, whose name, attributions, competences, autonomy, management, budgetary regime, organisation and operation were adjusted to Decree no. 41/2018, of 23 July, through Decree no. 34/2022, of 19 July, in the use of powers delegated by the Council of Ministers, pursuant to the provisions of article 1, paragraph 1 of Resolution no. 30/2016, of 31 October, amended by the sole paragraph of article 1 of Resolution no. 61/2020, of 2 December, the Interministerial Commission for the Reform of Public Administration resolves:

Article 1 The Organic Statute of the Central de Medicamentos e Artigos Médicos, Instituto Público, abbreviated as CMAM, IP, attached hereto and forming an integral part of this Resolution, is hereby approved.

It is the responsibility of the Minister who oversees the health sector, after hearing the Ministers who oversee the Public Service and Finance Sector, to approve the Internal Regulations of CMAM, IP, within sixty (60) days from the date of publication of this Resolution.

Art. 3: It is the responsibility of the Minister who oversees the health sector to submit the CMAM, IP Staff Chart for approval by the competent body within ninety (90) days of the date of publication of this Resolution.

Art. 4 This Resolution shall enter into force on the date of its publication.

Approved by the Interministerial Commission for the Reform of Public Administration, on 4 December 2023. - The President, *Adriano Afonso Maleiane*.

**Organic Statute of the Central de Medicamentos e
Artigos Médicos, Instituto Público**

CHAPTER I
General Provisions

Article 1
(Nature)

The Central de Medicamentos e Artigos Médicos, Instituto Público, abbreviated to CMAM, IP, is a management body for the supply chain of medicines, medical supplies and other health products for the public sector, endowed with legal personality and administrative autonomy.

Article 2
(Scope and headquarters)

1. CMAM, IP, has its headquarters in Maputo City and operates throughout the country.

2. Whenever the exercise of its activities so warrants, CMAM, IP, may create and extinguish central and intermediate warehouses and other forms of representation in any part of the national territory, subject to authorisation by the Minister who oversees the Health sector, after consulting the Minister who oversees the Finance sector and the State representative in the Province.

Article 3
(Object)

The purpose of CMAM, IP is to ensure the coordination and execution of the supply chain, namely the processes of planning, acquisition, direct import, storage, conservation and distribution of medicines, medical-surgical material for current use and other health products for all health units of the National Health Service.

Article 4
(Guiding Principles)

Within the scope of its activity, CMAM, IP is guided by the following principles:

- a) legality;
- b) pursuit of the public interest;
- c) equality and proportionality;
- d) ethics and good faith;
- e) decision;
- f) accountability;
- g) transparency;
- h) universal coverage at all levels of care;
- i) excellence and continuous self-evaluation;
- j) rationality;
- k) promoting participatory management;
- l) partnership;
- m) multisectorality; and
- n) uniqueness.

Article 5
(Duties)

1. The CMAM, IP, is responsible for the management of medicines and health products:

- a) planning and quantifying the needs for medicines, medical supplies and other health products for all the Department's health units of the National Health Service (NHS);
- b) centralised procurement of medicines, medical and surgical equipment and other health products for the NHS;
- c) direct import of medicines, medical and surgical equipment and other health products for the NHS;
- d) storage of medicines, medical and surgical supplies and other health products in the warehouses under its management;
- e) conservation of medicines, medical and surgical supplies and other health products throughout the supply chain;
- f) distribution of medicines, medical and surgical supplies and other health products to the depot of the NHS health unit;

- g)* formulating policy proposals and logistics strategy for medicines, medical and surgical supplies and other health products;
- h)* studies to develop an efficient logistics system for medicines, medical and surgical supplies and other health products;
- i)* coordinating the development of logistics management information systems in the NHS;
- j)* human resources management and development;
- k)* implementation of agreements, memorandum and partnerships with other national and international institutions;
- l)* management of the resources allocated by the State, as well as by other national and international organisations;
- m)* strategic and predictive management by objectives, based on deconcentration and delegation of responsibilities; and
- n)* carrying out other activities that may be determined by higher authority under the terms of the Decree redefining the nature, attribution and competences of CMAM, IP, and other applicable legislation.

2. The tasks described in paragraph 1 of this article are carried out in close collaboration with the other actors in the Ministry that oversees the health sector.

Article 6 (Competences)

In order to fulfil its duties, CMAM, IP has the following competence:

- a)* coordinating the planning of the needs for medicines and health products throughout the supply chain;
- b)* promoting the financing for the purchase of medicines, medical and surgical equipment and other health products for the public sector;
- c)* ensuring the implementation of policies and strategies for the logistics of medicines, medical and surgical supplies and other health products;
- d)* carrying out forecasting and statistical studies on the medicines supply and distribution system;
- e)* define the parameters of the information systems for pharmaceutical logistics to be adopted at the various levels of the supply chain and at the points of distribution of medicines for consumption in the public healthcare network;
- f)* establish key management indicators at the various levels of the supply chain and measure them regularly;
- g)* carry out internal audits and control the supply chain;
- h)* analyse and determine the best strategy and search method to be used to acquire the medicines and health products needed by the health system, taking into account their specific nature and obtaining the best price, within the framework of the applicable legislation;
- i)* carrying out invitations to tender and other bidding procedures for the purchase of medicines and health products, as well as other general goods and services necessary to regulate the functioning of the institution;
- j)* drawing up the supply contracts and providing all the conditions for their approval by the competent authorities;
- k)* organising the transport of medicines and health products to NHS health facilities;

- l)* ensure the application of equity and other relevant criteria in the distribution of products to all NHS health units;
- m)* monitoring the expiry dates of products in warehouses;
- n)* ensuring the appropriate conditions for storing and preserving products in the warehouse;
- o)* collaborate in the realisation of post-graduate and continuing training courses in the field of logistics for health personnel;
- p)* collaborate with educational institutions in the training of health logistics professionals at secondary and higher education levels;
- q)* valorising medicines, medical and surgical equipment and other health products in the NHS;
- r)* implementing agreements, memorandum and partnerships with other national and international institutions; and
- s)* ensuring the management of resources allocated by the State, as well as by other national and international organisations.

Article 7 (Supervision)

1. CMAM, IP, is supervised, sectorally, by the Minister who oversees the health Sector and, financially, by the Minister who oversees the finance sector.

2. The exercise of sectoral supervision includes the power to authorise, approve and homologate the following acts:

- a)* general policies, annual and multi-annual operating plans and the respective budgets;
- b)* approve the internal regulations;
- c)* propose the approval by the competent body of the Organic Statute and the Staff;
- d)* appoint the Director General, Deputy Director General and Technical Director;
- e)* creation and extinction of delegations or other forms of representation of CMAM, IP;
- f)* monitor performance, in particular with regard to the fulfilment of established objectives and goals;
- g)* revoke or extinguish the effects of unlawful acts practised by the CMAM, IP bodies in matters within their remit;
- h)* exercise disciplinary action over the members of the CMAM, IP bodies, under the terms of the applicable legislation;
- i)* order the carrying out of inspection, supervision or auditing of acts carried out by the bodies of CMAM, IP; *j)* approve all acts that require prior authorisation from the sectoral authority; and
- k)* carry out other acts of legality control.

3. The exercise of financial supervision comprises the following acts:

- a)* approve the investment plans;
- b)* approve the disposal of its own assets, under the terms of the applicable legislation;
- c)* monitor financial performance;
- d)* approve the contracting of internal and external current credit loans, with a repayment obligation of up to 2 years;
- e)* ordering financial inspections; and
- f)* carry out other acts of control, under the terms of the applicable legislation.

CHAPTER II
Organic System

Article 8
(Bodies)

CMAM, IP, has the following bodies:

- a) National Council of Pharmaceutical Logistics and Medical Items;
- b) Governing Board; and
- c) Sole Auditor.

Article 9

(National Council for Pharmaceutical Logistics and Medical Items)

1. The National Council for Pharmaceutical Logistics and Medical Items is a technical body that consults and coordinates activities within the scope of the management and operation of CMAM, IP;

2. The National Pharmaceutical Logistics and Medical Items Council is responsible for:

- a) assess the annual and multi-annual activity plans;
- b) to assess the information necessary to monitor the activity of CMAM, IP;
- c) issue recommendations with a view to improving the functioning of the services to be provided;
- d) give its opinion on the activity report and balance sheet, under the terms of the applicable legislation; and
- e) carry out other activities assigned to it by law.

3. The National Pharmaceutical Logistics and Medical Items Council has the following composition:

- a) The Minister of Health, who chairs it, is replaced by whoever he delegates in his absence or impediment;
- b) Director-General;
- c) Deputy Director-General;
- d) Director of Central Services;
- e) Head of the Public Institute Office;
- f) Autonomous Head of Central Department;
- g) Autonomous Head of Department;
- h) representative of central and intermediate warehouses;
- i) Director-General of the National Blood Service - SENASA, IP;
- j) National Director of Medical Assistance;
- k) National Director of Public Health; and
- l) Directors of Central and Provincial Hospitals.

4. Other technicians and experts may be invited to take part in the sessions of the National Pharmaceutical Logistics and Medical Items Council, depending on the matters to be dealt with, by appointment of the Chairman of the Council.

5. The National Pharmaceutical Logistics and Medical Items Council meets in ordinary session once a year and extraordinarily whenever convened by the Chairman of the Council, on his own initiative or at the request of at least a third of its members.

Article 10

(Governing Board)

1. The Governing Board is a deliberative body that coordinates and manages matters relating to the operation of CMAM, IP;

2. The Governing Board is responsible for:

- a) drawing up the annual and multi-annual activity plans, the respective budgets and ensuring their implementation;
- b) systematically monitor and evaluate the activity carried out, in particular the use of the resources made available to it and the results achieved;
- c) drawing up the activity report;
- d) harmonise the proposals for the periodic stocktaking reports of the Economic and Social Plan;
- e) authorise expenditure and the contracting of technical assistance services under the terms of the applicable legislation;
- f) study and analyse any other matters of a technical and scientific nature related to the development of CMAM, IP's activities;
- g) conclude internal and external programme contracts;
- h) define the guidelines for the organisation and operation of CMAM, IP, and propose the creation of new services, their extinction or modification;
- i) authorise the performance of overtime work by State officials and agents, and to authorise the payment thereof;
- j) decide on the hiring and management of staff;
- k) propose the appointment of staff to management positions;
- l) present the accountability documents in accordance with the law;
- m) systematically monitoring and evaluating the activity carried out by the services, making the different sectors responsible for the use of the resources placed at their disposal and for the results achieved in terms of the quality of the services provided;
- n) take cognisance of and determine the appropriate measures regarding the complaints and claims submitted;
- o) exercise the competence in disciplinary matters provided for by law, regardless of the legal employment relationship;
- p) monitor the implementation of the budget, applying measures to correct deviations from the realised forecasts;
- q) ensuring that contracts are properly executed and authorising the execution and payment of expenditure;
- r) to take the necessary measures for the conservation of the assets assigned to the development of its activity and to authorise the related expenditure, as provided for in the investment plan; and
- s) carry out other activities assigned to it by law.

3. The Governing Board is made up as follows:

- a) Director-General, who chairs it;
- b) Deputy Director-General;
- c) Director of Central Services;
- d) Head of Office of a Public Institute;
- e) Autonomous Head of Central Department; and
- f) Autonomous Central Bureau Chief.

4. Other technicians and experts may be invited to take part in the Governing Board's meetings, depending on the matters to be dealt with, as designated by the Director General.

5. The Governing Board meets in ordinary sessions every fortnight and extraordinarily whenever convened by the Director General.

Article 11

(General Management)

1. CMAM, IP, is headed by a Director-General, assisted by two Deputy Directors-General, one of whom is the Technical Director, all appointed by the Minister responsible for the health sector.

2. The Director-General and Deputy Directors-General shall serve for a period of four years, renewable once.

3. The term of office of the Director General and Deputy Directors General may be terminated before expiry by decision of the appointing authority, on just cause, without the right to any indemnity or compensation.

Article 12

(Powers of the Director-General)

It is the responsibility of the Director General of CMAM, IP:

- a) head CMAM, IP;
- b) chairing meetings of the Governing Board and ensuring the smooth running of the public institute;
- c) execute and enforce the law, resolutions and decisions of the Governing Board;
- d) coordinating the preparation of the annual activity plan of CMAM, IP;
- e) exercise powers of management and staff discipline;
- f) represent CMAM, IP, in and out of court;
- g) control the collection of CMAM, IP's revenue;
- h) ensure the import and distribution process, as well as the quality of the imported and distributed medicine;
- i) ensure that the conditions for receiving, dispatching and transporting medicines and health products meet the necessary requirements for a good state of conservation, in order to guarantee their quality, hygiene and safety at work;
- j) overseeing the management of CMAM's human resources, IP;
- k) appointing, removing and dismissing the senior staff of the central body, regional offices and other forms of local representation;
- l) propose to the Minister responsible for health the adoption or updating of legislation, policies and strategies;
- m) coordinating the execution of CMAM, IP's scientific research plan;
- n) ensure the efficient management of available resources;
- o) directing the external relations activities of CMAM, IP; and
- p) carry out other activities assigned to it by law or organic statute;

Article 13

(Powers of Deputy Directors-General)

The Deputy Directors-General are responsible for

- a) assist the Director-General in the performance of his duties;
- b) under the guidance of the Director-General, to coordinate the activities of CMAM, IP;
- c) substitute for the Director-General in his absences and impediments, according to the precedence defined by him;
- d) ensure the import and distribution process, as well as the quality of the imported medicine and distributed;
- e) monitor and guarantee that the execution of pharmaceutical acts, which are routinely carried out,

comply with the legislation relating to the exercise of the pharmaceutical profession;

- f) ensure that the conditions for receiving, dispatching and transporting medicines and health products meet the necessary requirements for a good state of conservation, in order to guarantee their quality, hygiene and safety at work;
- g) advising the Director-General on the adoption of rules and procedures necessary to ensure the quality of products circulating in the supply chain; and
- h) carry out the other activities entrusted to it by the Director General.

Article 14

(Sole Auditor)

1. The Sole Auditor is the body responsible for monitoring the legality, regularity and sound financial and asset management of CMAM, IP.

2. The sole auditor is appointed from among certified auditors through a public competition.

3. The mandate of the Sole Auditor is three years, renewable once.

4. The Sole Auditor is responsible for:

- a) regularly monitor and control compliance with applicable laws and decrees, budget execution, and the economic, financial and asset situation of CMAM, IP;
- b) analyse the accounts of CMAM, IP;
- c) to carry out prior checks and give its opinion on the budget, its revisions and amendments, as well as the business plan with a view to its budgetary coverage;
- d) issue an opinion on the annual management report and management accounts, including the legal certification of accounts;
- e) to give an opinion on the acquisition, rental, disposal and encumbrance of immovable property;
- f) give an opinion on the acceptance of donations, inheritances or legacies;
- g) give an opinion on the contracting of loans;
- h) keep the General Management informed of the results of its checks and examinations;
- i) draw up reports on its supervisory activities, including an overall annual report;
- j) proposing to the Directorate General that external audits be carried out when necessary or convenient;
- k) verify, supervise and assess the legality of the organisation and operation of CMAM, IP;
- l) verify the effectiveness of the mechanisms and techniques adopted by CMAM, IP, to provide public services;
- m) to assess the degree of response given by CMAM, IP, to requests from health units;
- n) to ascertain the level of alignment of the activity and budget plans adopted and implemented by CMAM, IP, with the government's objectives and priorities;
- o) to assess the degree of compliance with the technical and methodological instructions issued by the Minister responsible;
- p) to assess the degree to which the periodic targets set by CMAM, IP, and by the Minister responsible, have been achieved; and
- q) give its opinion on matters submitted to it by the General Management, the Administrative Tribunal and the entities

that form part of the State administration's internal control system.

5. The Sole Auditor is obliged to take part in the meetings of the General Management at which the report and accounts and the proposal for the plan and budget are analysed.

CHAPTER III

Structure and Functions of the Organic Units

Article 15

(Structure)

CMAM, IP, has the following structure:

- a) Central Quantification and Planning Service for Medicines and Health Products;
- b) Central Procurement Service for Medicines, Health Products and Others;
- c) Central Service for the Storage, Conservation and Distribution of Medicines and Health Products;
- d) Audit and Internal Control Office;
- e) Department of Administration, Finance and Human Resources;
- f) Department of Information Technology, Communication and Image; and
- g) Legal Advice Office.

Article 16

(Central Office for the Quantification and Planning for Medicines, Health Products and Other Products)

1. The Central Quantification and Planning Department for Medicines, Health Products and Other Products is responsible for:

- a) in the Quantification area:
 - i. guide CMAM, IP's quantification processes;
 - ii. coordinate the quantification of medicines and health products with all those involved in the health area, in accordance with established health policies;
 - iii. drawing up and maintaining an information system on overall supply needs;
 - iv. systematise the coding of medicines and health products.

b) in the Planning area:

- i. systematising the proposals for the Social and Economic Plan and State Budget (PESOE) and the institution's annual activity programmes;
- ii. scheduling and monitoring deliveries of agreed purchases and donations;
- iii. systematise priorities in line with available resources;
- iv. coordinating the financing and programming of donations of medicines and health products to the NHS;
- v. coordinating the preparation of investment plans and liaising with cooperation partners.

c) in the area of monitoring and evaluation:

- i. monitoring and evaluating the fulfilment of short, medium and long-term plans;
- ii. drawing up periodic evaluation reports on the supply of medicines and health products and on the planning instruments;

iii. promote performance improvement of the different organic units based on the analysis of the information produced;

iv. designing and updating performance indicators for the medicines and healthcare products logistics chain; and

v. promote the improvement on the collection and quality of the institution's data and accountability.

d) in the area of Studies, Policies and Strategies:

i. drawing up and monitoring the implementation of the institution's short-, medium- and long-term development programmes and projects;

ii. design projects that attract funding to support CMAM, IP's investment programmes;

iii. develop studies and research to improve CMAM, IP's logistics chain;

iv. formulate policy proposals and envisage development strategies for the logistics of medicines and health products in the short, medium and long term;

v. proposing national and international cooperation programmes, projects and actions;

vi. coordinating the implementation of national and international cooperation programmes, projects and actions;

vii. participate in the preparation of conventions and agreements with cooperation partners;

viii. promote the accession, conclusion and implementation of international conventions and agreements;

ix. coordinating the preparation and follow-up of strategic studies, investment plans and liaison with cooperation partners; and

x. to carry out other activities that are determined in accordance with the applicable legislation.

2. The Central Service for the Quantification and Planning for Medicines and Health Products is headed by a Director of the Central Services, selected in an open competition and appointed by the Minister who oversees the health sector.

Article 17

(Central Procurement Office for Medicines, Health Products and Others)

1. The Central Procurement Service for Medicines, Health Products and Other Products has the following functions:

a) in the area of procurement and imports:

i. drawing up the procurement plan for medicines, health products and other goods and services and keeping it up to date;

ii. preparing and carrying out the procurement processes for medicines, health products and other goods and services in accordance with the procedures laid down in current legislation;

iii. carrying out the import and customs clearance procedures for goods acquired or obtained by donation, ensuring their timely delivery to the recipient warehouses;

iv. executing and managing contracts; and

v. collaborate in drawing up Technical Specifications and/or Terms of Reference;

b) in the area of Analyses and Processes:

- i.* updating and maintaining CMAM, IP's database of prices for medicines and health products;
- ii.* propose to the regulatory body for public procurement procedures the inclusion of suppliers in its register of those barred from contracting with the state;
- iii.* assisting internal and external audits relating to the process of contracting and importing medicines, health products and other goods and services;
- iv.* propose contracting strategies and procedures to ensure greater efficiency in the procurement of medicines and health products; and
- v.* to carry out other activities that are determined in accordance with the applicable legislation.

2. The Central Procurement Service for Medicines, Health Products and Others is headed by a Director of the Central Services, selected in an open competition and appointed by the Minister who oversees the health sector.

Article 18

(Central Service for the Storage, Preservation and Distribution of Medicines and Health Products)

1. The functions of the Central Service for the Storage, Preservation and Distribution of Medicines and Health Products are:

a) in the area of Storage and Conservation:

- i.* draw up the operating procedures for CMAM, IP warehouses;
- ii.* oversee the management and operation of CMAM, IP's warehouses;
- iii.* guiding the processes of reception, quality control, storage and conservation of medicines and health products;

b) in the Distribution area:

- i.* guiding the process of dispensing and distributing Medicines and Health Products to NHS health units;
- ii.* managing the transport of medicines and health products to NHS health units; and
- iii.* carry out other activities that are determined in accordance with the applicable legislation.

2. The Central Service for the Storage, Preservation and Distribution of Medicines and Health Products is headed by a Director of Central Services, selected in an open competition and appointed by the Minister who oversees the health sector.

Article 19

(Department of Administration, Finance and Human Resources)

1. The functions of the Department of Administration, Finance and Human Resources are as follows:

a) in the area of Administration and Finance:

- i.* manage the assets of CMAM, IP, in accordance with the rules and regulations established by the State;
- ii.* ensuring the correct use, maintenance, protection and safety of the institution's facilities and equipment;
- iii.* ensure that the inventory of CMAM, IP's assets is realised and updated, in accordance with the applicable legislation;
- iv.* provide good working conditions for all state employees and agents assigned to CMAM, IP;

- v.* calculate the costs of the supply chain;
- vi.* ensuring the administration and management of the institution's archives and documentation;
- vii.* drawing up budget plans in accordance with the applicable legislation;
- viii.* managing and controlling the institution's financial resources, ensuring efficient spending;
- ix.* drawing up the periodic treasury plans and ensuring that they are complied with;
- x.* execute the budget in accordance with the applicable rules and regulations;
- xi.* ensure procedural, documentary and legal compliance in budget implementation;
- xii.* drawing up periodic budget and financial implementation reports; and
- xiii.* drawing up the Annual Report and Accounts to be submitted to the Administrative Court.

b) in the Human Resources area:

- i.* ensuring compliance with the General Statute for State Officials and Agents and other applicable legislation to the staff at CMAM, IP;
- ii.* drawing up and managing the establishment plan;
- iii.* implementing and monitoring the sector's human resources development policy;
- iv.* implementing the rules and strategies relating to health, hygiene and safety at work;
- v.* implement the social security rules for state employees and agents;
- vi.* managing the system of careers, remuneration and benefits of state officials and agents;
- vii.* implement and keep up-to-date the CMAM, IP SNGRHE, in accordance with the guidelines and standards defined by the competent bodies;
- viii.* coordinating the performance evaluation of CMAM IP state officials and agents, in accordance with the applicable legislation;
- ix.* implement activities within the scope policies and strategies of HIV and AIDS, Gender and People with Disability in the Civil Service; and
- x.* carry out other activities that are determined in accordance with the applicable legislation.

2. The Department of Administration, Finance and Human Resources is headed by an autonomous Head of Central Department, appointed by the Director General.

Article 20

(Department of Information Technologies, Communication and Image)

1. The functions of the Department of Information Technologies, Communication and Image are:

a) in the area of Information Technology:

- i.* propose policies concerning access, use and security of information technologies and communication;
- ii.* provide the technological infrastructure that supports the information system suitable for users;
- iii.* manage network and communication services;
- iv.* coordinate projects and processes for the development of information systems appropriate to the needs of the institution;

- v. ensure the implementation of the IT policy of public institutions;
 - vi. keeping prices and codes for medicines and health products up to date in all CMAM, IP information systems;
- b) in the area of Communication and Image:
- i. plan and develop an integrated communication and image strategy for CMAM, IP;
 - ii. promoting the dissemination of the most relevant facts about the life of CMAM,IP, and everything that can contribute to clarifying public opinion;
 - iii. manage CMAM, IP's publicity, advertising and marketing activities;
 - iv. liaising with the media and the public on matters relevant to CMAM, IP; and
 - v. carry out other activities determined by its superiors under the terms of the applicable legislation.

2. The Department of Information Technologies, Communication and Image is headed by an autonomous Head of Central Department, appointed by the Director General.

Article 21

(Internal Audit and Control Office)

1. The functions of the Audit and Internal Control Office are:
 - a) carrying out internal audits of the supply chain;
 - b) verify compliance with and fulfilment of the established standards and procedures on the operation, procurement, consumption of medicines and health products and cost recovery at all levels of the NHS distribution chain;
 - c) propose the revision and updating of management procedures at all levels of the distribution chain;
 - d) verify the implementation of the quality management system;
 - e) monitoring environmental impact studies in the context of environmental and social safeguards;
 - f) monitor the inspections, audits and external evaluations carried out at CMAM, IP;
 - g) evaluate the effectiveness of the internal control system in order to guarantee compliance with the regulatory, statutory, legal and contractual requirements applicable to the activities of CMAM, IP;
 - h) assessing potential risks in the management and distribution of medicines and health products; and
 - i) advising management on improving procedures; and
 - j) carry out other activities determined by its superiors under the terms of the applicable legislation.
2. The Audit and Internal Control Office is headed by a Head of Public Institute, appointed by the Director General.

Article 22

(Legal Advice Division)

1. The functions of the Legal Advice Office are:
 - a) ensuring compliance with and observance of the legislation applicable to the institution;
 - b) issue legal opinions on matters related to the institution's activities;

- c) assist the Director General and other CMAM IP officials, in activities representing the institution;
 - d) commenting on the formal aspect of legislative measures in the areas of the institution and collaborating in the study and preparation of draft legislation;
 - e) issue an opinion on disciplinary proceedings, the formal regularity of the investigation and the legal adequacy of the proposed penalty;
 - f) issue an opinion on the petitions and report to the competent bodies on the results; and
 - g) analysing and shaping contracts, agreements and other legal instruments; and
 - h) carry out other activities determined by its superiors under the terms of the applicable legislation.
2. The Legal Advice Division is headed by an autonomous Head of Central Division, appointed by the Director-General.

CHAPTER IV

Local Representations of CMAM, IP

Article 23

(Regional Delegation)

1. CMAM, IP is represented at local level by the Regional Delegation.
2. The Regional Delegation is headed by a Regional Delegate, appointed by the Minister who oversees the health area on a proposal from the Director General.
3. The Regional Delegation reports centrally to the Director General, without prejudice to liaising and coordinating with the State representative in the province.

Article 24

(Powers of the Regional Delegate)

The Regional Delegate is responsible for:

- a) represent CMAM, IP, before the authorities in the area of its delegation;
- b) directing the Regional Delegation and coordinating its activities, carrying out the acts necessary for its effective operation;
- c) manage and administer the human, financial and property resources assigned to the delegation, in accordance with the law;
- d) submitting to the Director General of CMAM, IP, the delegation's activity plan and the respective periodic reports on the implementation of programmed activities;
- e) supervise and inspect the activities of the supply chain in its area of jurisdiction; and
- f) exercise the other competences conferred by law or determined by higher authority under the terms of these bylaws.

Article 25

(Functions of the Regional Delegation)

The functions of the Regional Delegation are:

- a) carry out the work plan for the activities for which they are responsible;

- b) coordinating the activities of CMAM, IP, in the Medicines and Health Products supply network under its remit;
- c) propose the delegation's annual activity plan;
- d) ensure compliance and fulfilment of the rules and procedures established for the operation, procurement, consumption of medicines and health products and cost recovery in their area of jurisdiction;
- e) ensuring the implementation of the quality management system for medicines and health products;
- f) promoting the rational use of medicines and health products;
- g) to ensure the collection of revenue which it is responsible for collecting;
- h) Supervising the operation of the Medicines and Health Products warehouses in its supply network;
- i) drawing up and implementing the annual activity plans and budget in the area of its jurisdiction and submitting reports on their fulfilment;
- j) manage the material, financial and human resources existing in the supply network it oversees;
- k) liaise between CMAM, IP, and the local authorities, ensuring the fulfilment of the institution's duties and competences at this level; and
- d) carry out other activities determined by its superiors under the terms of these Bylaws and other applicable legislation.

Article 26

(Structure of the Regional Delegation)

The structure of the regional delegation is set out in the Internal Regulations of CMAM, IP.

CHAPTER V

Financial and Asset Management

Article 27

(Plan and Budget)

1. CMAM, IP's activity plans and respective annual budgets must be in line with the instructions issued by the supervisory bodies and in accordance with the government's strategies and plans, and must be submitted for approval to the Minister responsible for the sector by 30 July each year.
2. CMAM, IP must draw up the respective operating and investment budgets for each financial year, which are approved by the ministers responsible for the sector and finance.
3. CMAM, IP, must submit the budget execution reports and accounts to the supervising ministers, accompanied by the reports of the supervisory body, on a quarterly basis.

Article 28

(Reports and Accounts)

1. CMAM, IP, must draw up the following documents by 31 December of each year:
 - a) report of the general management, indicating how the objectives of CMAM, IP have been achieved and analysing their efficiency in the various fields of action;
 - b) balance sheet and income statement;

- c) cash flow statement.

2. The annual report of the Directorate General, the balance sheet, the profit and loss account, as well as the opinions of the Sole Auditor, the Internal Auditor and the External Auditor, must be published in the *Official Gazette* and in one of the country's most widely circulated newspapers, as well as on the CMAM, IP *website*.

3. The financial statements referred to in this article must be submitted for approval by the relevant ministers by 31 March of the following year.

Article 29

(Revenues)

1. The following constitute CMAM, IP revenues:
 - a) subsidies, donations, contributions or donations from any public or private, national or foreign organisations;
 - b) revenues from the dispensing of medicines in NHS health units; and
 - c) any others resulting from the activity of CMAM, IP, or that are attributed to it by law.
2. All revenue collected will be channeled to the single treasury account, under the terms of the applicable legislation, as own revenue and earmarked after collection.

Article 30

(Channelling of Revenue)

1. Once collected, CMAM, IP channels the revenue into the Treasury's Single Account, as own and earmarked revenue.
2. Within 5 working days, the Public Treasury will return to CMAM, IP, as a definitive earmarking, all the revenue transferred to the Single Treasury Account, under the terms to be defined by joint Order of the Ministers responsible for the sector and finance.
3. The revenue referred to in the previous paragraph is returned upon registration of needs in e-SISTAFE.

Article 31

(Financial Management)

1. The financial and asset management of CMAM, IP is governed by the rules applicable to state bodies and institutions, namely the State Financial Administration System Law, the State Treasury Regime and other applicable legislation.
2. CMAM, IP's annual activity plan and the respective operating and investment budget are submitted for approval by the Minister responsible for the sector by 30 July each year.

Article 32

(Expenses)

CMAM, IP's expenses include:

- a) the costs of operating them;
- b) the costs of training, retaining and managing its staff;
- c) the costs of acquiring, maintaining and conserving goods and equipment, services or facilities necessary for its operation and the performance of its duties; and
- d) the cost of purchasing, storing and distributing medicines and other health products for NHS health units.

Article 33

(Audit and accounts judgement)

1. CMAM, IP is subject to the rules and provisions in force and to the methodological principles of budgetary and accounting management for institutions governed by public law, endowed with administrative and patrimonial autonomy.
2. CMAM, IP's accounts for each financial year shall be submitted to the Administrative Court by 31 March of the following year.
3. CMAM, IP's accounts for each financial year are subject to internal auditing, whose opinion forms an integral part of the annual report, without prejudice to the opinion of the Sole Auditor.

Article 34

(Assets)

The following are CMAM, IP assets:

- a) state property assigned to it; and
- b) the universality of goods, rights or obligations donated by public or private, national or foreign institutions, organisations or entities.

CHAPTER VI

Staff and Remuneration Regime

Article 35

(Staff Regime)

1. CMAM, IP staff are governed by the General Statute of State Officials and Agents and other applicable legislation.
2. Exceptionally, employment contracts governed by the general regime may be signed when necessary to fulfil specific objectives or for seasonal work compatible with the nature of the duties.

Article 36

(Remuneration system)

Without prejudice to acquired rights, CMAM, IP staff shall be subject to the remuneration regime for State officials and agents.

Price - 60,00 MT