

Complied Pharmaceutical Legislation Decree-Law no. 495/99 of 18th November

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INFARMED's Statutory Law

The National Institute of Pharmacy and Medicines (INFARMED) was set up as a personalised service, as a result of the reorganisation of the Health Ministry's services under Decree-Law no. 10/93 of 15th January. This new structure tailored the administrative organisation to the growing importance of the problems relating to medicines and pharmaceutical activities in the context of the health system.

INFARMED's operation, in line with the organisational structure laid down by Decree-Law no. 353/93 of 7th October, and the change in the discipline required of the pharmaceutical industry at the national and Community level, call for a review of the legislation that set up INFARMED. This has a triple aim: to meet the new European challenges; to respond to the new technical, scientific and organisational needs and to solve some of the problems identified in the meantime.

The need to ensure a high level of public health protection in matters of medicinal and health products and to improve information for the public, also justify tailoring INFARMED's structure to these challenges.

In point of fact, following the publication of INFARMED's Statutory Law, there were very significant changes at the European Union level in regard to medicines. The setting up of the European Agency for the Evaluation of Medicinal Products meant that Member-States, in particular Portugal, had to make extra effort to take part in the Community bodies and to coordinate national and Community powers.

In addition to these circumstances is the equally growing need to strengthen the rules and control of sanitary products, now known as health products, in accordance with the Community legislation that has been and continues to be enacted.

On the other hand the duty, since 1998, to apply the European Medicinal Products Evaluation and Authorisation System, involves strategic changes to the evaluation and authorisation of medicines, both in terms of procedures and the strategy of each of the national authorities now competing with each other.

As regards new organisational needs, it soon became clear that INFARMED lacked a consultative body that would allow greater participation of the various institutional players in the pharmaceutical and medicine fields and shared management. To that end INFARMED will now have a consultative council.

At the structural level this legislation provides for a more flexible operational structure that should be permanently able to meet the new and growing demands that the health goods and health care market and companies face.

New structures of experts are set up which should exist outside the institutions, that is to say in the academic world, as are monitoring and consultative committees that reflect the needs of the markets and the remaining players in the specific realm of medicines, the pharmaceutical industry and health products.

The evaluation of medicines use, especially their economic evaluation, is one area that has drawn the Institute's increasing attention, which is why another technical committee with specific functions in this field has been set up.

The normal recruitment method shall be the individual employment contract, so as to allow a flexible response without restricting economic activities and the spread of new technologies. The management bodies are also modified so as to give them greater decision-making and strategic powers in order to meet the growing demand for information and communication between the European Union Member-State bodies operating in this sector and the competitive national environment.

Finally, it is deemed that the best format for the regulatory body is a public institute with administrative and financial autonomy and its own property that is subject to the legal framework for State-owned companies. A body of this nature is in a position to guarantee the technical capacity to deal with the other players in the sector, as well as the flexibility to act and take the decisions required to make it a strategic partner in the development and satisfaction of its partners and the general public.

The procedures laid down in Law no. 23/98 of 26th May were complied with.

Thus:

Under the terms of article 198 (1) (a) of the Constitution, the Government decrees as follows:

CHAPTER I

Aim, nature and powers

Article 1

Aim

The National Institute of Pharmacy and Medicines, set up by Decree-Law no.10/93 of 15th January shall be governed by this instrument.

Article 2

Nature

The National Institute of Pharmacy and Medicines, hereinafter referred to as INFARMED, is a public corporation with administrative and financial autonomy and its own property.

Article 3

Regulations

INFARMED shall be governed by the provisions of this law, its internal regulations and, in addition, by the regulations relating to State-owned companies.

Article 4

Supervision

1 - INFARMED shall pursue its activities under the supervision and aegis of the Health and Finance Ministers under the terms set out below.

2 - The Health Minister shall:

- a) Define INFARMED's basic aims, in order to allow it to plan its activities;
 - b) Monitor INFARMED's activities, calling for all necessary information and issuing guidelines and recommendations;
 - c) Undertake audits and inspections;
 - d) Define the parameters for any collective negotiations under the terms of the law.
- 3 - The Health and Finance Ministers shall supervise INFARMED's economic and financial dealings and shall have the power to:
- a) Approve pluriannual financial and work programmes;
 - b) Approve annual budgets and work programmes;
 - c) Approve accounting reports;
 - d) Approve fees to be charged for services provided;
 - e) Authorise the purchase and sale of fixed assets when the transactions involved are not foreseen in the approved budgets;
 - f) Authorise the taking out of loans.

Article 5

Territory and representation

- 1 - INFARMED shall pursue its activities in the whole of Portugal, notwithstanding the powers of the Autonomous Regions and the regional health authorities.
- 2 - The Health Minister may, by means of an administrative rule, define who shall represent INFARMED in Portugal and at the European Agency for the Evaluation of Medicinal Products.

Article 6

Powers

- 1 - INFARMED shall have powers to evaluate, authorise, regulate, inspect and control the manufacturing, distribution, sale and use of medicinal products for human and veterinary use, including plant-based and homeopathic products as well as health products, in line with the respective specific legislation and notwithstanding the legal powers of other bodies.
- 2 – For the purposes of this instrument health products mean:
- a) Cosmetics and personal hygiene products;
 - b) Non-active medical devices;
 - c) In vitro diagnosis medical devices;
 - d) Homeopathic pharmaceutical products.
- 3 – In particular, INFARMED shall:
- a) Contribute to the defining of general health policy, in particular the definition and implementation of policies regarding medicines for human use and health products, as well as, in conjunction with the Department of Veterinary Medicine, those for veterinary medicines;
 - b) Take part in the setting up of rules relating to research, manufacturing, distribution, sale and use of medicines for human use and health products, as well as, in conjunction with the Department of Veterinary Medicine, of veterinary medicines;
 - c) Ensure the evaluation, conformity inspection and quality control of medicines for human use and health products, as well as, in conjunction with the Department of Veterinary Medicine, of veterinary medicines;
 - d) Ensure the conducting of studies and issuing of opinions relating to the access to and use of medicines within the health system;

- e) Evaluate and inspect pharmaceutical activities;
- f) Manage medicinal and health products vigilance systems, in cooperation with the relevant international authorities;

- g) Ensure health professionals and consumers have access to the information required to ensure rational use of medicinal products for human and veterinary use and health products;
- h) Promote and support, in cooperation with national and foreign universities and other research and development institutions, the study of and research into the pharmaceutical science and technology, pharmacology, pharmacoeconomics, pharmacoepidemiology and biotechnology fields;
- i) Ensure, within the scope of its powers, that the State's international obligations are fulfilled, namely at the European Union level, in particular the European Agency for the Evaluation of Medical Products, as well as in the context of the Council of Europe, in particular the European Pharmacopoeia Commission, and the United Nations in the field of narcotic and psychotropic substance control.

Article 7

Cooperation with other bodies

In order to fulfil its responsibilities INFARMED may cooperate with other public, private and cooperative sector bodies, in particular business associations, universities or other institutions and National Health Service departments, by forming associations or other corporate bodies.

CHAPTER II

Governing bodies and departments

SECTION I

Governing Bodies

Article 8

Governing Bodies

INFARMED's governing bodies shall be:

- a) The Executive Board;
- b) The Audit Committee;
- c) The Specialist Technical Commissions;
- d) The Consultative Council.

SECTION II

Executive Board

Article 9

Composition

- 1 - The Executive Board shall consist of a president, two vice-presidents and two other members.
- 2 - Executive Board members shall be appointed by a joint order issued by the Prime Minister and the Health Minister.
- 3 - Termination of the president's office shall result in the simultaneous termination of the remaining board members' offices.

Article 10

Powers

- 1 - Within the framework of departmental organisation and operation and of daily management, the Executive Board shall:

- a) Direct INFARMED's activities;
- b) Draw up INFARMED's work programme, budget, annual report and management accounts, and submit them for Ministerial approval;
- c) Approve the internal structure and the various departments' functions, as well as the necessary internal regulations that may be required;
- d) Collect revenue and authorise expenditure;
- e) Manage INFARMED's property, by purchasing, selling, burdening, donating and leasing, actively and passively, fixed and current assets, as well as accepting donations and legacies, under the law and this instrument;
- f) Manage the INFARMED's human resources, including the signing of collective employment contracts;
- g) Appoint agents and representatives to other national and international bodies.

2 - As regard the regulation and control of the manufacturing, distribution, sale and use of medicinal and health products, the Executive Board shall:

- a) Prepare applications for marketing authorisations for medicinal products for human use and submit them to the Health Minister;
- b) Authorise the manufacturing and importing of medicinal products for human use;
- c) Authorise the marketing, manufacturing and importing of veterinary medicinal products, with the exception of immunological products;
- d) Undertake the necessary acts related to the sale and use of health products, pursuant to the applicable legislation;
- e) Issue an opinion as to the renewal of marketing authorisations;
- f) Issue an opinion as to the authorisation of modifications to previously authorised medicines;
- g) Issue an opinion as to the public dispensing classification of medicines;
- h) Order, under the law, a ban on the manufacturing, importing, distribution and sale of medicinal and health products, and, where necessary, suspend, revoke or declare expired authorisations granted previously and cancel the corresponding licenses;
- i) Order the withdrawal from the market or the seizure of medicinal and health products, whenever this is required to protect public health or to ensure compliance with the aforesaid administrative acts;
- j) Authorise the setting up and operating of establishments to distribute and sell medicinal products for human and veterinary use, namely medicine wholesalers, pharmacies and medicine outlets, as well as approve the classification list of those persons wishing to open or transfer a pharmacy;
- k) Order inspections and audits of the aforesaid establishments;
- l) Order the closing of the establishments referred to in i)¹, and, where necessary, suspend, revoke or declare expired authorisations granted previously and cancel the corresponding licenses;
- m) Direct the preparation of applications for medicine reimbursements and submit them to the Minister.

3 – The Health Minister may delegate its powers relating to pharmaceutical and medicine matters to the Executive Board who shall be entitled to subdelegate them.

¹ The reference to i) is wrong and should be taken to mean j).

Article 11

Meetings

INFARMED's Executive Board shall meet ordinarily once a week and extraordinarily whenever convened by the president or at the request of at least two of its members or the audit committee.

Article 12

Delegation of powers and assignment of responsibilities

- 1 – The Executive Board may delegate any of its operations to one or more of its members or to INFARMED senior staff who shall be entitled to subdelegate them,.
- 2 – The Executive Board may also assign to its members, at the president's suggestion, the management of several of the Institute's functions.
- 3 – The aforesaid assignment shall involve the delegation of the powers corresponding to the operations concerned.
- 4 - The Executive Board shall, in all cases, expressly set the limits of the delegated powers and state whether or not they may be subdelegated.
- 5 – The previous sections shall not prevent the Executive Board from taking on or revoking acts performed by the delegated or subdelegated person, whenever it deems necessary.
- 6 – All Executive Board members are required to follow up INFARMED's affairs generally and to comment upon them.

Article 13

Binding INFARMED

- 1 - INFARMED shall be bound by:
 - a) The joint signature of two Executive Board members, one of which is the president's or that of the person replacing him/her in his/her absence;
 - b) The signature of one Executive Board member who has been delegated the necessary power in writing by the Executive Board to undertake the specific act(s);
 - c) The signature of the person duly qualified to do so under the terms of article 14.
- 2 – Acts of day-to-day management which do not give rise to liabilities on the part of INFARMED may be signed by any Executive Board member or whosoever has been delegated the relevant power.

Article 14

Executive Board president

- 1 - The Executive Board president shall:
 - a) Convene, preside over and chair Executive Board meetings;
 - b) Represent INFARMED in dealings with the Ministers;
 - c) Represent INFARMED in and out of court;
 - d) Levy fines pursuant to the law.
- 2 – The president shall act as the board's delegate in matters that cannot wait until the next board meeting and which, not being day-to-day matters, require ratifying at the first meeting following their performance.
- 3 – When the Executive Board president is absent or unable to attend, he/she shall be replaced by the vice-president appointed for that purpose.

Article 15

Employment terms

1 - Executive Board members shall have the status of public managers, and shall receive salaries and perks equal to those of the Executive Boards and executive committees of group B State-owned companies.

2 - Executive Board members shall work full-time and shall be subject to the rules on incompatibility and impediments applying to holders of high public office and regulatory authority directors.

SECTION III

Audit committee

Article 16

Composition

1 – The audit committee shall consist of three members, one of which must be a chartered accountant, appointed by a joint order from the Finance and Health Ministers.

2 – Such order shall name the audit committee president.

Article 17

Powers

The audit committee shall:

- a) Audit the management of INFARMED and compliance with the legislation and regulations applying to its activities;
- b) Check compliance with Executive Board decisions;
- c) Periodically review INFARMED's financial and economic position and check the asset values;
- d) Monitor and regularly control performance of work programmes and annual budgets;
- e) Issue an opinion on INFARMED's budget, annual report and accounts and write an annual report on the committee's auditing activities;
- f) Issue an opinion as to the purchase, sale or burdening of fixed assets;
- g) Issue an opinion on any matter submitted to it by the Executive Board or any matter it deems appropriate;
- h) Inform the Executive Board of any irregularities found out and notify the appropriate authorities when so justified;
- i) Propose the undertaking of audits.

Article 18

Meetings

The audit committee shall ordinarily meet once a month and extraordinarily whenever convened by its president or at the request of any of its members.

Article 19

Employment terms

Audit committee members shall be subject to the rules and receive salaries equal to those of the audit committees of group B State-owned companies, notwithstanding the provisions of this instrument.

SECTION IV
Specialist technical commissions
Article 20

Specialist technical commissions

1 – The specialist technical commissions are INFARMED’s consultative bodies.

2 – The technical commissions consist of:

a) Medicinal Products Evaluation Commission, which shall generally issue opinions, whenever so requested, on matters relating to medicines, in particular marketing authorisations;

b) Pharmacovigilance Commission, which shall generally issue opinions, whenever so requested, on matters relating to pharmacovigilance and the workings of the National Pharmacovigilance System;

c) Pharmacoeconomics Commission, which shall generally assess, whenever so requested, economic evaluation studies provided by applicants and propose measures best suited to the studies’ aims in accordance with the higher interests of public health and the National Health Service;

d) Portuguese Pharmacopoeia Committee, which shall generally draw up, revise, update and construe the Portuguese Pharmacopoeia, as well as issue opinions, whenever requested, on related matters;

e) National Hospital Formulary of Medicinal Products Commission, which shall draw up, revise, update and monitor publication of the National Hospital Medicines Formulary, as well as issue opinions, whenever so requested, on related matters;

f) Medical Devices for In Vitro Diagnosis Evaluation Commission, which shall generally issue opinions, whenever so requested, on any technical matters relating to in vitro diagnosis devices and, in particular, on marketing authorisation applications for such devices;

g) Cosmetology Technical and Scientific Commission, which shall generally issue opinions, whenever so requested, on matters relating to cosmetics and personal hygiene products.

3 – The National Medicines Advertising Commission shall also operate under the auspices of INFARMED.

4 - The composition and workings of the technical commissions shall be defined by an administrative rule from the Health Minister.

5 – The commissions shall receive administrative support from a secretariat.

6 – Technical commission members shall be appointed, following a proposal from INFARMED’s Executive Board, by Order issued by the Health Minister or, in the case of members coming from other Ministries, by a joint Order issued by the Health Minister and the minister of the relevant department.

7 – Commission members’ remuneration shall be set by joint Order issued by the Ministers of Finance and Health and the Government member responsible for the Civil Service.

8 – Under an administrative rule issued by the Health Minister, other technical commissions may be set up if they prove to be necessary to the exercise of INFARMED’s powers, notwithstanding any special legislation.

SECTION V
Consultative Council
Article 21

Consultative Council

1 – The Consultative Council is INFARMED’s general consultative body.

2 – The Consultative Council shall consist of:

- a) The Executive Board members;
- b) The Health Director-General;
- c) The presidents of the Executive Boards of the regional health authorities;
- d) The Veterinary Director-General;
- e) The Trade and Competition Director-General;
- f) The president of the Consumers Institute;
- g) The regional directors for health of the Azores and Madeira Autonomous Regions;
- h) The president of the College of Physicians;
- i) The president of the College of Pharmacists;
- j) The president of the College of Veterinary Doctors;
- k) A representative of the pharmaceutical industry associations;
- l) A representative of the pharmacy associations;
- m) A representative of the medicinal products wholesaler associations;
- n) A representative of the cosmetic industry associations;
- o) A representative of the medical devices industry;
- p) A representative of the other health products industries monitored by INFARMED;
- q) A representative of the consumers associations;
- r) Three individuals of recognised merit, appointed by the Health Minister.

3 – The Consultative Council shall:

- a) Issue an opinion on INFARMED's annual and pluriannual working programmes;
- b) Issue an opinion, whenever so requested, on proposed legislation relating to matters concerning INFARMED's powers;
- c) Comment on any other matter of interest to INFARMED submitted to it by the Executive Board, and it may issue an opinion or recommendations.

4 – INFARMED's Executive Board president shall automatically be the Consultative Council president.

5 – The Consultative Council shall meet in plenary session ordinarily once every six months and extraordinarily whenever convened by the president, at his/her initiative or at the request of one third of its members. It may meet by sections in accordance with the internal regulations.

6 - The Consultative Council shall approve its internal regulations, which shall be approved by the Health Minister.

SECTION VI

Department coordination and organisation

Article 22

Coordination Areas

1 - INFARMED shall have the following coordination areas:

- a) Medicines and Health Products Evaluation and Vigilance Coordination;
- b) Licensing, Inspection and Control Coordination;
- c) Medicines Information and Use Coordination;
- d) Planning and General Administration Coordination.

2 – The Medicines and Health Products Evaluation and Vigilance Coordination Area covers:

- a) The medicines evaluation and marketing authorization process and their remaining on the market;

- b) The health products evaluation and marketing authorisation and their remaining on the market;
- c) The liaison of INFARMED's activities with those of other relevant national entities and departments in the area of health products;
- d) The development of INFARMED's capability in terms of clinical trials;
- e) INFARMED's representation at the Community and international levels, on committees and in working parties, in line with its powers.

3 – The Licensing, Inspection and Control Coordination Area covers:

- a) The licensing process for pharmaceutical establishments, in particular manufacturers, medicine wholesalers and pharmacies;
- b) The inspection of the above establishments, as well as the other operators involved in the medicinal and health products circuit, and the checking of whether the sale of medicinal and health products complies with the legislation in force;
- c) The quality checking of medicinal and health products.

4 – The Information and Use of Medicines Coordination Area covers activities relating to the evaluation of the medicine and health products market, namely:

- a) The watching of supply and demand and the accessibility of medicinal and health products and their circuits;
- b) The production of information for decision-making in line with the scientific and technical limits available;
- c) Information for health workers, consumers and decision-makers;
- d) The implementation of policies, defined at a higher level, covering control and economic evaluation of the medicinal and health products market.

5 – The Planning and General Administration Coordination Area covers:

- a) The planning, scheduling and evaluation of activities and of resource management;
- b) The organisation and running of information systems;
- c) The organisation and management of correspondence, document circuits and records;
- d) Financial, asset and human resource management.

6 - The Executive Board may opt to set up other coordination areas, or modify those laid down in no. 1 of this article, as well as set up technical advice offices under the terms of no. 1 of article 23.

Article 23

Departments

1 – The departments, their nature, organisation and powers shall be defined by internal regulations approved by the Executive Board and endorsed by an administrative rule from the Health Minister.

2 – The management levels and operational coordination shall be set out in the internal regulations to be approved by the Executive Board.

3 – Department heads shall be assigned under the terms of Decree-Law no. 404/91 of 16th October or under article 36 of law.

CHAPTER III

Property and finance regulations

Article 24

Property

INFARMED's property consists of all the assets, rights and liabilities it has acquired in its own name, as well as all State assets allocated to it in order to pursue its activities.

Article 25

Financial and property management

1 – INFARMED's financial and property management shall be governed by those rules applying to State-owned companies that are compatible with the nature of INFARMED.

2 – The following management tools shall be used to undertake the financial and property management:

- a) Working programme plans;
- b) Annual working programmes;
- c) Annual budget;
- d) Cash flow budget;
- e) Income Statement;
- f) Trial balance;
- g) Annual report and accounts.

3 - The annual working programmes shall set forth the projects to be undertaken during the year by the different departments.

4 – The budget shall be drawn up on the basis of INFARMED's working programme, notwithstanding the internal breakdowns required to decentralise responsibilities and to ensure proper management control.

5 – The annual report and accounts, together with the audit committee's opinion shall be presented within the legally established deadlines:

- a) for approval by the Finance and Health Ministers;
- b) for Tribunal de Contas (Audit Office) consideration.

6 – The Executive Board shall submit to the Audit Office only the management accounts and the prior auditing of acts and contracts relating to INFARMED's civil servants, pursuant to the Audit Office Organisation and Procedures Law.

Article 26

Revenue

1 – INFARMED's revenue consists of:

- a) The sums allocated by the Government's Budget;
- b) The fees charged for services rendered to public and private bodies;
- c) The fee laid down in Decree-Law no. 282/95 of 26th October, as well as the income from licenses, fees and fines, in accordance with the rules governing the activities monitored by INFARMED;
- d) The sums attributed to INFARMED in the context of European Union institutions, in particular the European Agency for the Evaluation of Medicinal Products;
- e) The subsidies, grants, donations and legacies provided by any national and international public or private bodies;
- f) The revenue from the sale of assets and rights pertaining to them;
- g) Bank deposit interest;
- h) The surplus from previous years carried forward;
- i) Transfers stemming from actions supported by European Community structural funds;
- j) Any other income arising under the law, an agreement or contract.

Article 27

Expenditure

1 – INFARMED’s expenditure consists of:

- a) The expenses arising from its departments’ operations and the fulfilment of the duties assigned to it;
- b) The cost of purchasing, constructing, maintaining and preserving the assets, equipment or services it employs.

2 - INFARMED may award subsidies to not for profit bodies in regard of activities related to the pursuit of INFARMED’s duties.

3 - INFARMED may offer paid training placements or scholarships under the terms of the relevant internal regulations.

Article 28

Accounting system

1 – INFARMED’s revenue and expenditure shall be recorded using the Official Public Accounting Code (POCP).

2 – Budgets and annual accounts shall be presented in accordance with the aforesaid Code.

Article 29

Realisation principle

INFARMED’s accounts shall comply with the realisation principle.

Article 30

Stock valuation

1 - INFARMED shall record all of its property using suitable valuation criteria, in line with the principles laid down in the POCP.

2 – Fixed assets shall be depreciated as per the rules laid down in the POCP.

3 – Fixed assets shall be revalued at suitable intervals, employing the rates set by the Finance Minister.

Article 31

Debt collection

1 – Amounts owed to INFARMED in the form of compulsory fees or other revenue laid down herein or recognised by Ministerial Notice shall be subject to enforced debt collection by means of tax recovery proceedings, governed by the Taxation Proceedings Code and brought by the appropriate fiscal justice department. The fees and other revenue shall be treated as debts to the State.

2 – For the purposes of the above section, the Executive Board shall issue a certificate stating the sum owed, in accordance with the provisions of articles 249 and 250 of the Tax Code.

Article 32

Purchase of goods and services

The purchase of goods and services shall be governed by Decree-Law no. 197/99 of 8th June.

CHAPTER IV

Staff

Article 33

Staff regulations and structure

1 - INFARMED staff shall comply with their individual employment contracts and the internal regulations, notwithstanding the working conditions set out in the collective regulations.

2 – The maximum limits for overall INFARMED staff contracts shall be set in the annual working programme and budget.

Article 34

Social security

1 - INFARMED employees shall be obliged to enrol in the general social security scheme, although they may opt to retain the social protection they enjoyed at the time they were hired, by means of a written declaration submitted to INFARMED.

2 - INFARMED shall contribute to the social security schemes to which its employees belong, paying the sums laid down for employer's contributions by those schemes.

3 – In relation to employees covered by the civil service social protection scheme, including Executive Board members, INFARMED shall make a monthly contribution to the scheme equal to that paid by those employees.

4 - Executive Board members shall be subject to the general social security scheme set out in Decree-Law no. 327/93 of 25th September, unless they are civil servants or agents appointed on a requisition or assignment basis, in which case they may opt for the civil service social protection scheme under the conditions laid down in section no. 5.

5 – Staff who opt for an individual employment contract may choose to retain the civil service social protection scheme, by means of a declaration. The deductions payable shall be based on the entire income arising from the position held at INFARMED, and that income shall be used to calculate the pension earned.

Article 35

Incompatibilities

INFARMED staff and members of the specialist technical commissions are forbidden from being members of the governing bodies of the companies or other entities subject to INFARMED regulation, from holding any position in them or providing any service, remunerated or not, and from receiving any sums from them.

Article 36

Mobility

1 – Civil servants and employees of public institutes and local authorities, as well as the employees of State-owned companies and companies with public share capital, may be called upon to work for INFARMED, being requisitioned, seconded or assigned following authorisation from their original employer. They shall be guaranteed their position in their original place of employment and shall retain all rights acquired there. The time worked at INFARMED shall be deemed time worked in their position at their original employer.

2 - INFARMED employees may work for the State in public institutes, local authorities, State-owned companies and companies with public share capital under the terms of the above section.

3 – Employees working for INFARMED under the terms of no. 1 shall remain in the social security scheme provided by their original employer, namely in regard to pension, retirement, death and sickness benefits.

CHAPTER V

Final and transitional provisions

Article 37

Individual employment contract options

1 – Members of the civil service who are on INFARMED’s permanent staff or who are employed on an assignment, requisition or secondment basis may opt for an individual employment contract.

2 – Notice of that option shall be given to the Executive Board in the form of a notarized private document and shall result in the vacating of the civil service position the employee held from the time the individual employment contract is signed.

3 – The internal regulations setting out the working conditions for staff who signed an individual employment contract shall be approved within 60 days of this law coming into force.

Article 38

Length of service

In the case of employees who opt for an individual employment contract, the entire length of their service as a civil servant shall be taken into account for the purposes of length of service, pensions, retirement and other benefits.

Article 39

Civil Service membership

1 – Staff who, after this Act comes into effect, do not opt for an individual employment contract shall continue to be bound by civil service regulations, although they shall retain the right to leave the civil service at any time.

2 – For the purposes of the previous section, the non-management positions among INFARMED’s permanent staff, approved by Administrative Rule no. 1114/93 of 3rd November, as amended by Administrative Rules no. 32/95 of 13th January and 329/96 of 3rd August shall remain. Those positions shall be extinguished from bottom to top as they are vacated.

3 –As regard the staff occupying the aforesaid positions, the Executive Board shall exercise the powers attributed to the Director-General of the Civil Service, notwithstanding the delegation of those powers.

4 – Staff on long-term leave shall be subject to the legislation governing the return of staff working for departments that are closed, restructured or subject to a change in regulations.

Article 40

Applications

Any job applications for the positions referred to in article 39 (2) that have already been or are being processed at the time this law comes into effect shall stand, notwithstanding the provisions of 38

Article 41

Assignments

When this Act comes into effect all staff assigned to management positions shall cease to be so assigned but shall continue to exercise their day-to-day management functions until new managers are appointed, notwithstanding the provisions of article 32 of Law no. 49/99 of 22nd June.

Article 42

Head of Office

1 – The Heads of Office posts laid down in the annex to Administrative Rule no. 1114/93 of 3rd November which established INFARMED’s permanent staff structure, as required by article 21 (1) of Decree-Law no. 353/93 of 7th October, are hereby extinguished.

2 – The staff affected by the previous section shall become class 1 technical officers. The corresponding positions shall be created among INFARMED's higher technical staff in order to implement the provisions of the previous section.

3 – Administrative Rule no. 1114/93 of 3rd November shall be amended by an Order for the Health Minister and the Government member responsible for the Civil Service.

Article 43

Legislation revoked

Decree-Law no. 353/93 of 7th October and article 13 (2) of Decree-Law no. 10/93 of 15th January are hereby revoked.

Seen and approved by the Council of Ministers on 9th September 1999. - *António Manuel de Oliveira Guterres - António Luciano Pacheco de Sousa Franco - Jorge Paulo Sacadura Almeida Coelho - Joaquim Augusto Nunes de Pina Moura - Victor Manuel Coelho Barros - Maria de Belém Roseira Martins Coelho Henriques de Pina - Eduardo Luís Barreto Ferro Rodrigues.*

Promulgated on 29th October 1999.

Published.

The President of the Republic, *JORGE SAMPAIO.*

Countersigned on 4th November 1999.

The Prime Minister, *António Manuel de Oliveira Guterres.*