

**Internal Regulation of the National Institute of Pharmacy
and Medicinal Products**

(approved by deliberation of the Management Board of January 20th 2003)

CHAPTER I

General Arrangements

Article 1

Purpose

This Regulation establishes the principles of management, the organisational structure of the National Institute of Pharmacy and Medicinal Products (INFARMED), as well as the powers assigned to the Services that integrate it and to which reference is made in Article 23 (1) of Decree- Law No.495/99 of November 18th.

Article 2.

Rules of Management

The management of INFARMED is based on the following principles:

- 1st. INFARMED develops its activity in the fields of pharmacies, medicinal products for human and veterinary use, as well as of health products, directing its intervention to the assurance of the access of the citizens to medicinal and health products with quality, safety and efficacy , promoting their adequate and rational use;
- 2nd. INFARMED develops its activity in obedience to the principles of independency, transparency, accessibility of interested parties and confidentiality of technical-scientific data contained in the dossiers of which it is the trustee;
- 3rd. The structure of INFARMED is based on an organisation and management functionally assuring the performance evaluation as well as the adequate responsibility of the ruling structure;
- 4th. The structural organs of INFARMED connect each other according to the parameters of a supplier-customer relationship through definition of the contributions and pertaining results, according to the dispositions of this Regulation as well as of activity plans defined;
- 5th. The responsibilities and participation of every INFARMED collaborator will be supported by an internal contractual system and a code of conduct.

6th. Adoption of quality management mechanisms, either at an internal or at an external level.

Article 3

Internal and external clients

1 – Every organ and collaborator of INFARMED are considered internal clients.

2 – Every singular or collective person having any type of connection with INFARMED and specially:

- a) citizens;
- b) singular and collective agents and entities, belonging to the areas of pharmacy, medicinal and health products;
- c) public and private agents and entities ,either singular or collective , health services suppliers or those who develop relevant activities at technical and scientific areas regarding health, medicinal and health products fields;
- d) economic agents belonging to the sectors included in the scope of duties of INFARMED

are considered external clients.

Article 4

Structure and organisation

1 – INFARMED is organised in the following co-ordination areas:

- a) Co-ordination area of medicinal and health products evaluation and surveillance;
- b) Co-ordination area of inspection, licensing and control;
- c) Co-ordination area of medicinal products information and use;
- d) Co-ordination area of planning and general management.

2 – The structure of INFARMED is composed by operative services, organised in directorates, departments and sectors integrating combinations of specialised activities defined according to their nature and competencies, as well as by supportive services with the competencies and organisation defined in this Regulation.

3 – The directorates ensure the management of one or more departments or sectors depending on them, as well as the practice of duties and tasks delegated or subdelegated to them by the Management Board.

4 – The directorates, as well as the supportive services, depend directly on the Management Board or on one of its members, in case of delegation of powers by the Management Board.

5 – The directorates are organised in departments and/or in sectors defined according to their technical-scientific, technical and administrative nature or to the technological knowledge required by the activity to be developed.

Article 5

Direction and co-ordination

1 – The directorates, departments, sectors and supportive services are conducted, taking into account the principles established in article 2nd by directors of directorate and department or by co-ordinators of sector, according to the dispositions of this Regulation, subject to individual labour agreements in the system of service commission, as referred in Article 23(3) Decree-Law No.495/99 of November 18th. or service commission foreseen in Article 36. of the same legal act.

2 – The directors of directorate and department and the sector co-ordinators are appointed by the Management Board, among the candidates with the training and experience adequate to the functions, by selection methods previously established by the same Board.

3 – The termination of directors and co-ordinators service commissions is determined by the Management Board.

CHAPTER II

Operative Services

Section I

Co-ordination area of medicinal and health products evaluation and surveillance

Subsection I

Directorate of Medicinal and Health products (DMH)

Article 6

Competences

The Directorate of Medicinal and Health Products (DMPS) is assigned the following competences:

- a) To ensure the necessary activities to the procedures of evaluation and marketing authorisation of medicinal products for human and veterinary use and to their maintenance in the market;
- b) To ensure the necessary activities to the procedures, evaluation and authorisation of special use authorisation applications regarding medicinal products for human use;
- c) To ensure the necessary activities to the marketing of medical devices;
- d) To ensure the necessary activities to the registration of homeopathic pharmaceutical products;
- e) To ensure the necessary activities to the registration and marketing authorisation of other products that, according to the Law, come to be included in INFARMED assignments;
- f) To ensure the activities inherent to INFARMED intervention in the mutual recognition and centralised procedures and community referrals;

- g) To co-operate in the inspection of good clinical practices , according to its competences;
- h) To ensure the elaboration of rules and guidance's destined to INFARMED services users;
- i) To ensure the co-ordination with the medicinal products evaluation commission;
- j) To ensure the co-ordination of INFARMED with the Technical Commission for Veterinary Medicinal Products;
- k) To ensure the co-ordination of INFARMED with the Medical Devices for in-vitro diagnosis evaluation commission;
- l) To ensure the articulation with national and European information systems within the scope of its competences;
- m) To collaborate in the representation of INFARMED, either at community or at international level, in commissions and working parties, within the scope of its competences.

Article 7

Structure

1 – DMH comprises the following departments:

- a) Department of Medicinal Products for Human Use;
- b) Department of Medicinal Products for Veterinary Use;
- c) Department of Medical Devices.

2 – The Department of Medicinal Products for Human Use is assigned the following competences:

- a) To manage the procedures regarding applications for marketing authorisation, as well as the variations and renewal of marketing authorisation of medicinal products for human use;
- b) To manage the activities regarding INFARMED's intervention in the mutual recognition procedure, namely as a reference Member State, as well as in centralised procedure and in community referrals;
- c) To grant special use authorisations(AUE) of medicinal products for human use;
- d) To manage procedures regarding registration and marketing authorisation of medicinal and homeopathic pharmaceutical products;
- e) To validate information included in databases;
- f) To organise and keep a file on registration dossiers and evaluation follow up;
- g) To ensure the secretariat of the Medicinal Products Evaluation Commission;
- h) To ensure the articulation with national and European information systems within its competences.

3 – The Department of Medicinal Products for Veterinary Use has the following competences:

- a) To manage the procedures regarding applications for marketing authorisation, as well as the variations and renewal of the marketing authorisation of medicinal products for veterinary use;
- b) To ensure the necessary activities for the evaluation of efficacy, safety and quality of medicinal products for veterinary use in the areas of chemistry, biology and pharmaceutical technology, toxicology and pharmacology and of veterinary medical practice and their maintenance on the market;
- c) To elaborate the evaluation report, updating it whenever a new information relevant in terms of quality, efficacy and safety is made available;
- d) To manage the procedures regarding the granting AUEs on veterinary medicinal products and of medicinal products for hospital use;
- e) To ensure the technical support to the functioning of the Technical Commission for Veterinary Medicinal Products, namely through the articulation with INFARMED's representatives.

4 – The Department of Medical Devices has the following competences:

- a) To manage, evaluate and monitor applications regarding CE marking on medical devices;
- b) To manage, evaluate and monitor procedures regarding marketing of medical devices and *in vitro* diagnosis medical devices, according to the regulations in force, namely medical devices and *in vitro* diagnosis medical devices manufacturers and distributors registration, communication of medical devices and *in vitro* diagnosis medical devices and marketing authorisation of medical devices and *in vitro* diagnosis medical devices;
- c) To manage, evaluate and monitorize procedures regarding medical devices clinical research;
- d) To manage and evaluate notifications regarding evaluation of *in vitro* diagnosis medical devices functional behaviour;
- e) To organise and keep files regarding dossiers registration and evaluation follow-up;
- f) To ensure the articulation with national and European information systems within its competences;
- g) To monitor clinical research with medical devices;
- h) To provide secretarial support for the functioning of the Commission on Evaluation of In Vitro Diagnosis Medical Devices.

5 –Dependent of DMPS functions a sector on Community Affairs that ensures, namely, the intervention and co-ordination of activities inherent to the participation of the different departments of this Directorate in the structures and community working parties, namely of the European Agency for the Evaluation of Medicinal Products.

Article 8

Direction and co-ordination

DMPS is managed by a director of directorate and each of the departments is managed by a director of department and the sector is managed by a co-ordinator of sector.

Subsection II

Directorate of Risk Management and Epidemiological Studies

Article 9

Competences

The Directorate of Risk Management and Epidemiological Studies (DGREE) is assigned the following competences:

- a) To ensure the co-ordination and functioning of the Pharmacovigilance National System of Medicinal Products for Human Use, according to the Decree-Law no.242/2002 of November 5th;
- b) To manage the Pharmacovigilance and vigilance alert system of health products of the European Union and to ensure the participation in the monitoring program of WHO medicinal products;
- c) To promote and carry out epidemiological studies;
- d) To co-operate with other national and international entities in the fostering and holding of studies in the area of medicinal and health products epidemiology;
- e) To ensure the articulation with national and European information systems within the scope of its duties;
- f) To ensure the articulation with the Pharmacovigilance Commission;
- g) To co-operate in the representation of INFARMED at community and international level in commissions and working parties, within its competences.

Article 10

Structure

1 – The Directorate of Risk Management and Epidemiological Studies (DGIZEE) comprises the following departments:

- a) Department of Pharmacovigilance;
- b) Department of Vigilance of Health Products;
- c) Department of Medicinal Products and Health Products Epidemiology.

2 – The Department of Pharmacovigilance has the following competences:

- a) To collect, evaluate and spread information on suspected medicinal products adverse reactions;
- b) To monitor clinical trials through collection, registration and evaluation of adverse events happening during those trials;
- c) To analyse the existence of causality relationships between medicinal products and adverse reactions occurred;

- d) To ensure premature identification of safety problems that might occur when medicinal products are used;
- e) To co-ordinate activities of Pharmacovigilance units that integrate the Pharmacovigilance National System;
- f) To ensure articulation with national and European information systems within its competences;
- g) To ensure relationship with EMEA Pharmacovigilance group as well as with the Pharmacovigilance centres of other medicinal products agencies;
- h) To suggest and implement safety measures;
- i) To elaborate benefit – risk reports;
- j) To ensure relationship with INFARMED internal and external clients regarding medicinal products safety;
- k) To provide the secretarial support for the Pharmacovigilance Commission;
- l) To ensure the urgent spreading of safety by health professionals and by the public in general;
- m) To co-ordinate the publication of the Pharmacovigilance Bulletin;

3 – In the dependence of the Department of Pharmacovigilance exists a specific sector of adverse reactions to medicinal products that, within the scope of the Pharmacovigilance National System of Medicinal Products for Human Use ensures, namely, the competences mentioned in paragraphs a) to f).

- 4 – The Department of Vigilance of Health Products has the following competences:
- a) To collect, register, evaluate and spread information on adverse events associated to the use of health products or to incidents with medical devices;
 - b) To manage the vigilance alerts system of health products at the European Union;
 - c) To promote and implement safety measures;
 - d) To ensure necessary activities to collection, registration and spreading of information on adverse events associated to health products use or incidents with medical devices and promote and implement safety measures, as well as to make a benefit – risk analysis.

5 – The Department of Medicinal and Health Products Epidemiology has the following competences:

- a) To promote and carry out epidemiological studies, either of a quantitative, or qualitative nature, within the scope of usage and monitorisation of medicinal and health products;
- b) To promote and carry out epidemiological studies to support decision , namely regarding possible safety problems associated to the use of medicinal and health products;
- c) To promote and carry out studies for the identification of psychological, sociological and cultural factors associated to the prescription and use of medicinal and health products;
- d) To promote and develop tools to support the clinical decision and the use of medicinal products, namely electronic ones;
- e) To collect data on consumption within the scope of safety evaluation of drugs and health products;

- f) To ensure INFARMED intervention in national and community programs within the scope of its competences, namely in areas such as antibioresistance and the rational use of medicinal products.

Article 11

Direction and co-ordination

DGREE is managed by a director of directorate, each of the departments is managed by a director of department and the sector by a co-ordinator of sector.

Subsection III

Directorate of Technical-Scientific Evaluation

Article 12

Competences

The Directorate of Technical-Scientific Evaluation has the following competences:

- a) To ensure the necessary activities to the evaluation of efficacy, safety and quality of medicinal products for human use and their marketing;
- b) To evaluate and issue opinions about periodic safety reports and safety studies;
- c) To issue technical-scientific opinions about quality, safety and performance of health products;
- d) To ensure, in articulation with other services and commissions, the intervention of INFARMED in the activities of scientific counselling and evaluation at community level, namely within the scope of the European Agency for the Evaluation of Medicinal Products;
- e) To ensure the necessary activities for the authorisation of applications of clinical trials with medicinal products for human use;
- f) To grant AUEs of experimental medicinal products within the scope of clinical trials with humans;
- g) To articulate the evaluation with INFARMED Technical Commissions experts and with INFARMED technicians whenever adequate;
- h) To ensure articulation with national and European information systems within its competences;
- i) To co-operate in INFARMED representation at community and international level in commissions and working parties, within its competences.

Article 13

Structure

1 – DATC comprises the following departments:

- a) Department of Pharmaceutical Evaluation;
- b) Department of Pharmacology;
- c) Department of Clinical Trials.

2 – The Department of Pharmaceutical Evaluation should ensure the development of activities inherent to the evaluation of the quality and safety of medicinal products, including experimental ones, in the areas of chemistry, biology, pharmaceutical technology and toxicology, as well as to issue opinions about health products incorporating medicinal substances or biological products or other health products.

3 – The Department of Pharmacology should ensure the development of activities inherent to the efficacy and safety of medicinal products for human use and experimental medicinal products within the scope of clinical trials, as well as to issue opinions about health products incorporating medicinal substances or biological products or other health products.

4 – The Department of Clinical Trials has the following competences:

- a) To manage the procedures regarding clinical trials authorisation applications with medicinal products for human use;
- b) To manage the procedures regarding experimental medicinal products AUEs granting within the scope of clinical trials for human use;
- c) To ensure the articulation with European databases for registration of clinical trials for human use.

Article 14

Direction and co-ordination

DATC is managed by a director of directorate and each of the departments is managed by a director of department.

Section II

Area of Licensing Co-ordination, Inspection and Control

Subsection I

Directorate of Inspection and Licensing

Article 15

Competences

The Directorate of Inspection and Licensing (DIL) has the following competences:

- a) To elaborate and suggest technical rules about installation and functioning of manufacturers, wholesalers, pharmacies and public and private hospital pharmaceutical services, including definition of essential minimum human and technical resources;
- b) To ensure the necessary activities for licensing of manufacturers, wholesalers and pharmacies, as well as of public and private hospital pharmaceutical services;

- c) To ensure necessary activities and initiatives for inspection of research and development activities regarding producers of raw-materials for pharmaceutical use, manufacturers, wholesalers, pharmacies and public and private pharmaceutical services, as well as other agents intervening in the circuit of medicinal and health products, and verification of the conformity of applicable rules in production and marketing of medicinal and health products;
- d) To ensure the inherent activities of the rapid alert system regarding medicinal and health products;
- e) To ensure the competences regarding monitorisation of medicinal products advertising, monitoring, labelling and package leaflet of medicinal and health products;
- f) To ensure the representation and co-operation of INFARMED in pharmaceutical inspection activities at an international level, including mutual recognition agreements;
- g) To ensure the development of pharmacovigilance inspection responsibilities and inspection of good clinical practices linked with clinical trials with medicinal and health products;
- h) To propose the inception and ensure the inquiry of processes regarding the application of the right of mere social classification belonging to its duties;
- i) To ensure the fulfilment of international obligations of the Portuguese Government near the United Nations Organisation and the activities inherent to the licensing of agents intervening in the circuit of narcotic and psychotropic substances and the monitoring of the authorised activities of cultivation, production, manufacturing, use, bulk marketing, distribution, import, export, transit, purchase, sale, delivery and retaining of plants, substances and preparations of restricted use;
- j) To ensure the organisation and integrated management of INFARMED technical archive regarding dossiers of pharmacies, wholesalers and laboratories of medicinal and health products as well as of products and substances of controlled use;
- k) To co-operate in the representation of INFARMED at community and international level in commissions and working parties, within its competences;
- l) To issue positions regarding the industrial licensing of activities of raw-materials for pharmaceutical use and medicinal products manufacturing.

Article 16

Structure

1 – DIL comprises the following departments:

- a) Department of Licensing;
- b) Department of Inspection;
- c) Department of Cosmetics and Monitoring of Health Products Market.

2 – The Department of Licensing has the following competences:

- a) To ensure the inherent activities to the licensing of pharmacies, public and private hospital pharmaceutical services, manufacturers, wholesalers and

other agents intervening in the circuit of medicinal products and health products;

- b) To ensure the fulfilment of international responsibilities of the Portuguese Government near the United Nations Organisation as well as the activities inherent to the licensing of agents intervening in the circuit of narcotic and psychotropic substances.

3 – The Department of Inspection, besides the bearing of the remaining duties of inspection and monitoring ascribed by law to INFARMED, has the following competences:

- a) To inspect pharmacies and hospital pharmaceutical services whether public or private;
- b) To inspect manufacturers, wholesalers and other agents intervening in the circuit of medicinal products, from the starting material up to the finished product, as well as the verification of conformity of their manufacturing with the legislation in force;
- c) To control the advertisement, labelling and package leaflet of medicinal products;
- d) To ensure the fulfilment of pharmacovigilance inspections, vigilance of health products and good clinical practices in articulation with the Directorate of Risk Management and Epidemiological Studies and the Directorate of Technical-Scientific_Evaluation;
- e) To ensure the control of manufacturers, wholesalers and other agents intervening in the circuit of health products, from the starting material up to the finished product, as well as the verification of conformity of their manufacturing and marketing with the legislation in force;
- f) To control the authorised activities of cultivation, production, manufacturing, use, wholesale, distribution, import, export, transit, purchase, sale, delivery and apprehension of plants, substances and preparations of restricted use;

4 – The Department of Cosmetics and Monitoring of Health Products Market has the following competences:

- a) To develop the activities of cosmetic and body hygiene products registration and ingredients confidentiality application evaluation;
- b) To ensure the activities of monitoring of the market of cosmetic and body hygiene products, medical devices, homeopathic products, as well as of other products within the competences of INFARMED;
- c) To support the control of manufacturers, wholesalers and other agents intervening in the circuit of cosmetic and body hygiene products, from the starting material up to the finished product, as well as the verification of conformity of their manufacturing and marketing with the legislation in force.

Article 17

Direction and co-ordination

DIL is managed by a director of directorate and each of the departments is managed by a director of department.

Subsection II

Directorate of Quality Assurance

Article 18

Competences

The Directorate of Quality Verification (DCQ) by means of the adequate management of the laboratory, shall ensure the quality verification of medicinal and health products, through the development of the following activities:

- a) To participate in the quality assurance system for medicinal products, ensuring the analytical control of medicinal products in the market;
- b) To proceed to the official release of batches of medicinal products of biological origin;
- c) To support the assessment of pharmaco-toxicological quality and safety within the granting of medicinal products marketing authorisations ;
- d) To participate in the quality assurance system for health products;
- e) To participate in co-operation studies with other national or foreign official entities, in mutual recognition procedures, methods verification and reference standards;
- f) To ensure and promote scientific research activities within the scope of medicinal and health products quality and safety, namely through the development of specific programs and co-operation with other institutions;
- g) To ensure INFARMED duties for the monitoring of good Laboratory Practices, according to OECD principles;
- h) To perform studies within the scope of starting-materials, pharmaco-technological formulation and development, medicinal products production and control, for public and private entities;
- i) To ensure the participation in the European Network of Official Medicines Control Laboratories;
- j) To co-operate in the representation of INFARMED at community and international level, including the European Pharmacopoeia, commissions and working parties, within the scope of its competences.

Article 19

Structure

1 – DCQ comprises the following departments:

- a) Laboratory of Pharmacotechnics and Biopharmacy;
- b) Laboratory of Pharmaceutical Chemistry;
- c) Laboratory of Biology and Biotechnology;
- d) Department of Microbiology;

2 –Dependent of DCQ there is an unit of quality assurance which responds to the Advisor of Quality Management , where quality audits to the services are concerned. Its competences are:

- a) To ensure the duties of INFARMED regarding the National Follow-up Program of Good Laboratory Practices, according to OECD principles.
- b) To manage the quality system, including co-ordinating the Quality Handbook and its procedures elaboration and support
- c) ;
- d) To plan and perform internal audits;
- e) To develop and analyse internal programs of quality control;
- f) To follow-up inter-laboratorial trials in which DCQ takes part;
- g) To co-ordinate, under the director's guidance, the activities pertaining to laboratorial logistics, connected with activities planning and the management of resources.

3 –Dependent of DCQ acts the co-ordinator for Research and Development, which duties are:

- a) To co-ordinate research projects developed within the competences of INFARMED;
- b) To elaborate research and development proposals and their co-ordination, which require the contribution of other directorates, departments or sectors of INFARMED;
- c) To co-ordinate research and development activities promoted in partnership with other national and foreign scientific institutions;
- d) To provide scientific advice, at internal and external level, in projects and activities of scientific nature.

Article 20

Direction and co-ordination

DCQ is managed by a director of directorate and each of the departments is managed by a director of department.

Section III

Area of information and use of medicinal products

Subsection I

Directorate of Medicinal and Health Products Economics

Article 21

Competences

The Directorate of Medicinal and Health Products Economics (DEMPS) has the following competences:

- a) To ensure INFARMED duties regarding reimbursement of medicinal products by the National Health Service;

- b) To monitor the accessibility as well as the circuits and access of citizens to medicinal and health products;
- c) To make the prospective identification of innovations regarding medicinal and health products and evaluate their possible impact on public health and NHS;
- d) To ensure the collecting and treatment of information about the use of medicinal and health products;
- e) To co-operate with national and international entities in the fulfilment of studies in the area of medicinal and health products , namely those deriving from the accomplishment of development strategies of the pharmaceutical sector;
- f) To maintain in execution the policies of pharmaco-therapeutic and economic control and evaluation of the medicinal and health products market, with special incidence on reimbursed medicinal products;
- g) To analyse and promote studies of pharmaco-therapeutic and economic evaluation of medicinal products to support the decision of the Government reimbursement in the price of medicinal products;
- h) To ensure the collection of economic and statistical data regarding the sector of medicinal and health products;
- i) To make the periodic evaluation of the medicinal products reimbursement system performance;
- j) To follow-up the prices evolution of medicinal products for human use reimbursed by the National Health Service, as well as the procedures of the pertaining regimen;
- k) To ensure the articulation with the Pharmaco-Economics Commission;
- l) To co-operate in the representation of INFARMED at community and international level, in commissions and working parties, within the scope of its competences.

Article 22

Structure

1 – DEMPS comprises the following departments:

- a) Department of Economic Evaluation and Health Results;
- b) Observatory of Medicinal and Health Products.

2 – The Department of Economic Evaluation and Health Results shall ensure the following activities:

- a) Analysis, promotion and accomplishment of economic studies for the control and evaluation of medicinal and health products market;
- b) Analysis and promotion of economic evaluation studies to support the State reimbursement decision in the price of medicinal products;
- c) Accomplishment and economic evaluation of the decisions for the sector of medicinal and health products;
- d) Pharmaco-therapeutic evaluation to support the State reimbursement decision in the price of medicinal products;

- e) Pharmaco-therapeutic evaluation in order to support the analysis, promotion and accomplishment of economic studies for control and evaluation of the medicinal and health products market;
 - f) Secretariat support to the Pharmaco-Economics Commission;
 - g) Follow-up of the evolution of prices of medicinal products for human use reimbursed by NHS, as well as the procedures of the pertaining regimen.

3 – The Observatory of Medicinal and Health Products shall ensure the following activities:

- a) To monitor the access conditions to medicinal and health products market;
- b) To monitor the evolution trends of medicinal and health products market;
- c) To ensure the collection and treatment of information about the use of medicinal and health products;
- d) To collect and update statistical data regarding medicinal and health products sector;
- e) To treat and produce information to support decision making, medicinal products use monitoring and inclusion in economic studies.

Article 23

Direction and co-ordination

DEMPS is managed by a director of directorate and each of the departments is managed by a director of department.

Subsection II

Directorate of Information, Communication and External Affairs

Article 24

Competences

The Directorate of Information, Communication and External Affairs (DICAIE) has the following competences:

- a) To ensure the elaboration and production of information instruments adequate to the needs of health professionals;
- b) To ensure the elaboration and production of information instruments adequate to the various addressees of INFARMED activities;
- c) To ensure the functioning of the Information Centre of Medicinal and Health Products;
- d) To ensure the functioning of the Scientific and Technical Documentation Centre;
- e) To ensure a communication platform, as well as the external relations, namely in institutional co-operation affairs;
- f) To ensure the functioning of INFARMED meetings centre;
- g) To ensure the organisation of technical-scientific events under the responsibility of INFARMED;

- h) To ensure the co-ordination, participation and response of the Portuguese intervention in European institutions and international organisations of the sector;
- i) To ensure the co-ordination of information regarding INFARMED participation in commissions, committees and working parties at European Union level;
- j) To ensure INFARMED articulation with the services of the Ministry of Health regarding community affairs;
- k) To support the control of medicinal products advertising, in articulation with the National Council of Medicinal Products Advertising;
- l) To co-operate in the representation of INFARMED in commissions and working parties, according to its competences.

Article 25

Structure

1 – DICAЕ comprises the following sectors:

- a) Sector of Communication and Institutional Relations;
- b) Sector of Community Affairs, Co-operation and International Relations;
- c) Sector of Specialised Information.

2 – The Sector of Communication and Institutional Relations has the following competences:

- a) To co-ordinate the activities regarding INFARMED image and internal and external communication, including public relations and the media;
- b) To implement and maintain an informative system about INFARMED and any matters concerned to it;
- c) To ensure the publication of INFARMED information documents;
- d) To ensure the organisation of technical-scientific events under the responsibility of INFARMED;
- e) To ensure the functioning of INFARMED meetings centre;
- f) To co-operate in the representation of INFARMED in commissions and working parties, according to its competences;
- g) To ensure the secretariat support to the Commission of Portuguese Pharmacopoeia and Commission of National Hospital Formulary of Medicinal Products;
- h) To ensure the co-ordination and support to the working party responsible for the elaboration of the therapeutic handbook.

3 – The Sector of Community Affairs, Co-operation and International Relations has the following competences:

- a) To ensure the co-ordination of activities in which INFARMED takes part, at community and international level;
- b) To ensure the co-ordination of the information regarding INFARMED participation in commissions, committees and working parties of the Council

of the European Union, of the European Commission, of the European Agency for the Evaluation of Medicinal Products and others.

- c) To ensure the activities of international co-operation;
- d) To ensure the articulation of INFARMED with the pertaining services of the Ministry of Health regarding community affairs;
- e) To co-operate in the representation of INFARMED in commissions and working parties, according to its competences.

4 – The Sector of Specialised Information has the following competences:

- a) To collect, prepare, produce and spread information on medicinal and health products;
- b) To identify and guarantee the satisfaction of the information necessities of INFARMED external customers;
- c) To organise and maintain technical and scientific information regarding medicinal and health products;
- d) To organise and maintain a multimedia documentation centre;
- e) To ensure the information management and maintenance at the INFARMED site on Internet;
- f) To ensure the activities inherent to the functions of the Medicinal Products and Health Products Information Centre, including the offer of a Blue Line and specialised communication channels directed for health professionals and for citizens.

5 - Dependent of the Sector of Specialised Information operates a technical and scientific documentation centre responsible for the organisation and maintenance of technical and scientific information in the intervention areas of INFARMED.

Article 26

Direction and co-ordination

DICAE is managed by a director of directorate and each of the sectors by a co-ordinator of sector.

Section IV

Area of planning co-ordination and general administration

Subsection I

Directorate of Technologies and Information Systems

Article 27

Competences

The Directorate of Technologies and Information Systems (DTSI) has the following competences:

- a) To plan, to elaborate studies and to formulate proposals leading to the permanent development of the information and communication systems;
- b) To promote the integration of the standard operative procedures (PON) within the scope of the information system, as well as to monitor its filing, cataloguing and updating;
- c) To ensure the global management of the information system;
- d) To define interfaces with other information systems in the health area, at national and European Union level;
- e) To issue certificates on medicinal products, as defined by the World Health Organisation;
- f) To guarantee the fulfilment of the permanent development of applications and information and communication systems and their adequacy to the users needs, as well as to their integration, implantation and maintenance;
- g) To give support to the users and to foster the study of new computing methods and tools;
- h) To configure, install and maintain in adequate exploration the substructures of the communications network, the operative systems, the base applications and the computing equipment;
- i) To ensure the representation of INFARMED at community and international level in commissions and working parties, within its competences.

Article 28

Structure

1 – DSTI comprises the following departments:

- a) Department of Information Systems;
- b) Department of Technological Substructures.

2 – The Department of Information Systems has the following competences:

- a) To guarantee the reliability and updating of information regarding medicinal and health products;
- b) To manage the medicinal and health products database ;
- c) To co-ordinate the activities of standardisation and harmonisation of concepts, definitions and terminologies related to medicinal and health products;
- d) To issue certificates within the scope of WHO Certification System of Quality of Pharmaceutical Products in Circulation and International Commerce, as well as other deemed necessary;
- e) To ensure the fulfilment of information systems and define the *interfaces* with other information systems in the health field, at national and European Union level;
- f) To co-operate with the remaining services in carrying out tests to the applications, defining documentation rules and guaranteeing the performance, safety and confidentiality of information;
- g) To develop the applications of information systems for management;
- h) To define the logic and physical model of the databases and ensure their management and optimising and procedures standardisation;

- i) To elaborate the technical specifications, follow up the development, the implementation, the test and maintenance of applications purchased outside;
- j) To support the applications implementation, either at a software updating level, or at a training level.

3 – The Department of Technological Substructures shall ensure the following activities:

- a) To control and optimise the installed equipment;
- b) To test and ensure the installation of logic base supports and product-programs;
- c) To manage software versions of application base that have been installed;
- d) To suggest new network architectures or updating of the existing ones and ensure adequate levels of availability and reliability;
- e) To manage computing supports;
- f) To define rules and standards and technical support in the use of hardware and software;
- g) To support the decisions making about the adoption of computing products and solutions;
- h) To guarantee the maintenance, performance and safety conditions of installed products and their safety, giving support to search and controlling the fulfilment of technical rules;
- i) To co-ordinate and supervise the communications infrastructures and keep them operational;
- j) To ensure the updating and installation of hardware and software;
- k) To participate in procedures of computing goods and services purchase.

Article 29

Direction and co- ordination

DTSI is managed by a director of directorate and each of the departments is managed by a director of department.

Subsection II

Financial and Patrimonial Directorate

Article 30

Competences

The Financial and Patrimonial Directorate (DFP) has the following competences:

- a) To participate in the definition of the financial and budgetary policies;
- b) To execute the financial, budgetary and acquisition of goods, services and repairs policies;
- c) To elaborate the annual and the ready-cash budgets and control and analyse regularly its execution;

- d) To elaborate the management accounts and the annual financial report ;
- e) To carry out the funds management and perform the collection of revenues and the payment of expenses;
- f) To organise, elaborate and keep updated the patrimonial and accounting records;
- g) To ensure the registration and filing of original contracts producing responsibilities or rights of a patrimonial or financial nature, except those regarding the staff;
- h) To ensure the administrative management of the procedures for the acquisition of goods, services and repairs, according to the legislation in force;
- i) To ensure the stocks management and the procurement of goods and services needed and adequate to the functioning of the Institute;
- j) To promote, ensure and follow up the projects elaboration and the repairs execution;
- k) To ensure the adequate maintenance and technical assistance to goods, equipments, buildings and facilities;
- l) To manage the properties and furniture belonging to INFARMED, as well as the Government goods affected to it;
- m) To ensure the safety and communications systems management of vehicles and external spaces;
- n) To rent and lease real estate and mobile goods;
- o) To co-operate in the representation of INFARMED at community and international level in commissions and working parties, according to its competences.

Article 31

Structure

1 – DFP comprises the following departments:

- a) Department of Financial and Budgetary Management;
- b) Sector of Treasury;
- c) Department of Accounting;
- d) Sector of Procurement and Assets.

2 – The Department of Financial and Budgetary Management has the following competences:

- a) To implement and participate in the definition of the financial and budgetary policy;
- b) To elaborate and implement economic-financial and budgetary analysis;
- c) To elaborate the annual financial report;
- d) To elaborate, execute and control the budget;
- e) To keep the management board informed about the budgetary execution;
- f) To ensure the administrative management of the acquisition procedures of goods, services and repairs, according to legislation, including the exercise of contracts subject to a previous visa of the Court of Auditors.

3 - Dependent of the Department of Financial and Budgetary Management there is the Treasury Sector, that ensures the fund and cash management through the following activities:

- a) To elaborate and control the ready-cash budget;
- b) To carry out the collection of revenues and the payment of expenditures;
- c) To elaborate ready-cash financial analysis:

4 – The Department of Accounting has the following competences:

- a) To organise, elaborate and keep updated the accounting registrations and procedures inherent to the general and analytical accounting system;
- b) To define, organise and maintain cost centres;
- c) To organise and keep the accounting files;
- d) To ensure the registration and filing of the original contracts originating responsibilities or rights with a patrimonial or financial nature, except those regarding the staff;
- e) To elaborate the management account as well as the annual report and accounts.

5 – The Sector of Procurement and Assets shall fulfil the following duties:

- a) To ensure the *stocks* management and the procurement of goods and services necessary and adequate to the functioning of the Institute;
- b) To promote, ensure and follow up the elaboration of projects and the execution of repairs;
- c) To ensure the adequate maintenance and technical assistance of goods, equipments, buildings and facilities and manage the pertaining contracts;
- d) To manage the properties and furniture belonging to INFARMED, as well as the Government goods affected to it;
- e) To ensure the safety and communications systems management of vehicles and external spaces;
- f) To rent and lease real estate and mobile goods;
- g) To promote, ensure and follow up the elaboration of procedures regarding the acquisition of goods and services and repairs, within the scope of its activities;
- h) To participate in the definition of financial and budgetary policy.

Article 32

Direction and co-ordination

DFP is managed by a director of directorate, each of the departments is managed by a director of department and each of the sectors by a co-ordinator of sector.

Subsection III

Administrative and Human Resources Directorate

Article 33.

Competences

The Administrative and Human Resources Directorate (DARH) has the following competences:

- a) To organise and ensure the staff management services, including the assiduity control and the organisation of a control system of displacements on duty;
- b) To participate in the policy definition and ensure the elaboration and management of the human resources plan;
- c) To organise, elaborate and co-ordinate the professional training programs,
- d) To participate in the negotiations of collective work conventions;
- e) To manage the careers, performance evaluation and staff information systems;
- f) To manage the health, hygiene and work safety system;
- g) To ensure activities inherent to the staff recruitment, selection and reception;
- h) To ensure the fulfilment of every legal duty regarding human resources;
- i) To participate in the definition of human resources financial and budgetary policies;
- j) To ensure reception, registration, classification, distribution and dispatch of all the documents received and forwarded by INFARMED;
- k) To ensure the publication of any act and decision of INFARMED of compulsory publication, either in the Official Journal or in the media;
- l) To ensure the activities inherent to the regulation, organisation and classification, maintenance, availability and maintenance of INFARMED files not included in the duties of other services;
- m) To co-operate in the representation of INFARMED in commissions and working parties, according to its competences.

Article 34

Structure

1 – DARH comprises the following sectors:

- a) Sector of Staff Management and Careers Development;
- b) Sector of Dispatch and Archive.

2 – The Sector of Staff Management and Careers Development has the following competences:

- a) To co-operate in the definition of human resources policy and ensure its fulfilment;
- b) To ensure the information on the staff;
- c) To elaborate and co-ordinate the human resources plan;
- d) To elaborate and co-ordinate the plan and training projects fulfilment;
- e) To ensure the elaboration of applications to financing for professional training;
- f) To perform the staff selection, recruitment and reception;

- g) To elaborate the individual work contracts and rendering of services of an intellectual and scientific nature;
- h) To propose and ensure all the disciplinary proceedings;
- i) To plan and co-ordinate the performance evaluation fulfilment;
- j) To plan and control the careers progression;
- k) To elaborate the social balance;
- l) To collaborate in the negotiations of the work collective regulations;
- m) To keep updated the individual files of employees and co-workers;
- n) To control the staff assiduity;
- o) To elaborate the working hours charts, the staff registration and the holidays plan as well as the wages sheet, allowances and discounts;
- p) To ensure an organisation and control system of duty displacements;
- q) To register and pay the wages, allowances and discounts;
- r) To ensure the legal duties of INFARMED, namely those regarding hygiene, safety and medicine at work.

3 – The Sector of Dispatch and Archive has the following competences:

- a) To ensure the reception, registration, classification, distribution and dispatch of all the documents received and forwarded by INFARMED;
- b) To ensure the publication of any act and decision of INFARMED of compulsory publication, either in the Official Journal or in the media;
- c) To ensure the activities inherent to the regulation, organisation and classification, maintenance, availability and keeping of INFARMED archive.

Article 35

Direction and co-ordination

DARH is managed by a director of directorate and each of the sectors by a co-ordinator of sector.

CHAPTER III

Supportive Services

Section I

Legal Office

Article 36

Competences

The Legal Office (GJC) is a supportive service with the following duties ascribed:

- a) To ensure the legal advice to the management board and remaining services of INFARMED;
- b) To carry out studies regarding alterations to the legislation in force within the scope of INFARMED activity, as well as to ensure the legislative production in its intervention area;

- c) To issue advices, to answer consultations and, in general, to elaborate legal studies and documents within the scope of INFARMED activity;
- d) To check the regularity and the conformity to law of contracts and business regarding the pharmacies property;
- e) To ensure the representation in court, either directly or in the system of external services acquisition, in the procedures where INFARMED is a party;
- f) To ensure information and support necessary to the preparation and follow up of procedures, namely judicial and administrative ones, where INFARMED or any of its services are involved;
- g) To ensure the connection between INFARMED and its legal agents and follow up the pertaining activity;
- h) To propose the opening and ensure the inquiry of procedures regarding the application of the right of mere social distribution being of its duty;
- i) To issue certificates about procedures trusted to it;
- j) To co-operate in the preparation of internal regulations;
- k) To negotiate the work collective regulation and ensure the relationship with trade unions associations representative of INFARMED workers;
- l) To ensure the follow up of the evolution of community Law and regulatory affairs in fields belonging to INFARMED duty areas, as well as to co-ordinate procedures of transposition of community directives into internal law and to ensure the aspects of legislation implementation relevant to the regulatory practice;
- m) To participate in the international fora about regulatory affairs;
- n) To co-operate in the representation of INFARMED at national, community and international levels in commissions and working parties, according to its competences.

Article 37

Direction

GJC is managed by a director of directorate.

Section II

Sector of Planning and Management Control

Article 38

Competences

The sector of Planning and Management Control (SPCG) is a supportive service with the following duties ascribed:

- a) To organise and ensure the process of strategic and operational planning;
- b) To define and ensure the strategic and operational control as well as the periodic evaluation of the responsibility centres performance, through the adequate instruments;
- c) To participate in the definition of the financial and budgetary policy;

- d) To organise, elaborate, co-ordinate and monitor the execution of the annual activities plan;
- e) To prepare the annual activities report;
- f) To organise and ensure the normal functioning of an information system regarding planning and management control;
- g) To co-operate in the representation of INFARMED in commissions and working parties, according to its competences.

Article 39

Co-ordination

SPCG is managed by a co-ordinator of sector.

Section III

Advisory Body for Quality Management

Article 40

Competences

1 – The Advisory Body for Quality Management (AGQ) is a supportive service with the following duties ascribed:

- a) To ensure the co-ordination of policies and procedures definition, taking into account the orientation to the client;
- b) To evaluate the organisational performance through the monitoring of the pertaining indicators and to support plans for the quality improvement;
- c) To follow up the definition and suitability of the organisation instructions and rules, updating and rationalisation of administrative procedures and circuits which may influence the activities performance;
- d) To carry out the procedures evaluations, whenever required by the management board;
- e) To control the fulfilment of the defined procedures, for functioning of the services in a quality perspective .

2 – The AGQ level is defined by deliberation of the management board.

CHAPTER IV

Other structures

Section I

Advisory Body

Article 41

1 – The president of the management board shall have access to specialised advisors, namely in the areas of strategic information.

2 – Advisors are appointed by decision of the president of the management board.

Section II

Interlocutor with the Pharmaceutical Industry

Article 42

Nature

In the terms of the deliberation of the Ministers Council No. 133/2002, of September 25th., in the dependence of INFARMED, works the Interlocutor with the Pharmaceutical Industry, having as a mission to foster the support and counselling in specific areas.

CHAPTER V

Final and transitory dispositions

Article 43

Commissions and working parties

1 – INFARMED disposes of specialised technical commissions and working parties which articulate with the services of INFARMED depending on their competences and in the terms of the present Regulation.

2 – The management board is entitled to establish commissions, working parties or project teams, with adequate functional framing in order to face punctual needs, namely of a technical or scientific nature and providing they are transitory ones.

Article 44

Coming into force

The present Regulation comes into force within 30 days after the publication in the Official Journal of the decree that ratifies it.