ADMINISTRATIVE LAW

"Unravelling the Administrative Pathology Between Our Health Systems"

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DISCLAMER / ABSTRACT

While the present work has as its goal to expose this fascinating subject, it does not intend to reach any conclusion. It is merely an expositive comparison between our two Administrative Legal Systems.

I. INTRODUCTION

The present work, carried out in the context of the subject of Administrative Law, under the regency of Professor Doutor Vasco Pereira da Silva, has as its object the comparison between two equivalents technical commissions that give opinions and regulate functions regarding drugs and medical devices.

However, these are fundamentally different in their definition. As it will be discussed onward, even though both have very similar powers and functions, they have distinct characterisations depending on whose Legal System we observe them through.

With this in mind, I will establish a comparative study on two distinct forms of public administration in the Pharmaceutical Sector, the American Food and Drug Administration (FDA) and the Portuguese National Drugs and Heath Products Authority (INFARMED).

II. PORTUGUESE ADMINISTRATIVE LAW

Within the Portuguese Legal System, the public administrative organisation is regulated in the Constitution of the Portuguese Republic.

Regarding Portuguese Administrative Law, the portuguese public administration has as its primary task the satisfaction of collective needs by the society through services that are organised and kept by it.

Public Administration is formed by organs, among them, some have a technical nature and play an indispensable role in the preparation and making of decisions and their execution as well.[1]

Public administration also includes legal persons, which in turn can have a private or public nature.

This is why when we address the subject of privatisation, we refer ourselves to public legal persons who, to achieve effectiveness, will become private legal persons.[2]

Therefore, there are three levels of privatisation: The first level, that reports itself to the privatisation of public companies; the second level, which results in the State's interference within private companies and the third one, which refers to the institutions from the civil society, that regularly and continually cooperate with the State in the pursuit of public interests.

The administrative organisation can be deconcentrated (the creation of different legal persons) and the decentralised (the making of deciding powers) which are both typical forms foreseen in the Portuguese Administrative Law that are fundamental to the understanding of our Legal System.[3]

Another substantial aspect of the Portuguese Administrative Legal System is the hierarchy. That is an internal organisation vertical model that focuses on the distinction between superior and subordinate.

The traditional vertical Administration's organisation model is made up of two or more organs and agents with equal attributions, connected by a legal link that empowers the superior with directorial power and imposes in the subordinate the duty to obey.[4]

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[1] AMARAL, Diogo Freitas de, *Curso de Direito Administrativo – Vol. I*, Almedina, Coimbra, 2020, passim 193-354.
[2] Ibidem.
[3] Ibidem.
[4] Ibidem.

Furthermore, the superior also has four powers over the subordinate. It has directorial powers, supervision powers (either by its initiative or in consequence of hierarchic appeal), disciplinary powers and inspection powers. The subordinate, on the other hand, only has the obligation of following the orders and instructions of their hierarchic superiors.

We can also observe in this Legal System the delegation of powers. This is the act by which an Administration organ, usually the one that is competent to decide on the specific matter, allows, within the law, that another organ or agent to practice administrative acts in the aforementioned subject.[5]

The delegation of power also has some requirements, such as the necessity of a law that specifically states that an organ may concede powers to another, the so-called authorisation law. Because in our Legal System, the competence to deliberate is both unwavering and inalienable and can only exist if the law establishes it. This norm results from the CRP's Article 111º/2 and is reinforced by the Administrative Process Code's Article 36º.

In addition, power delegation requires the existence of two organs, or an organ and an agent, from the same public legal person, or of two distinct legal person organs, of which one must be the competent and the other that will eventually become competent on the matter.[6]

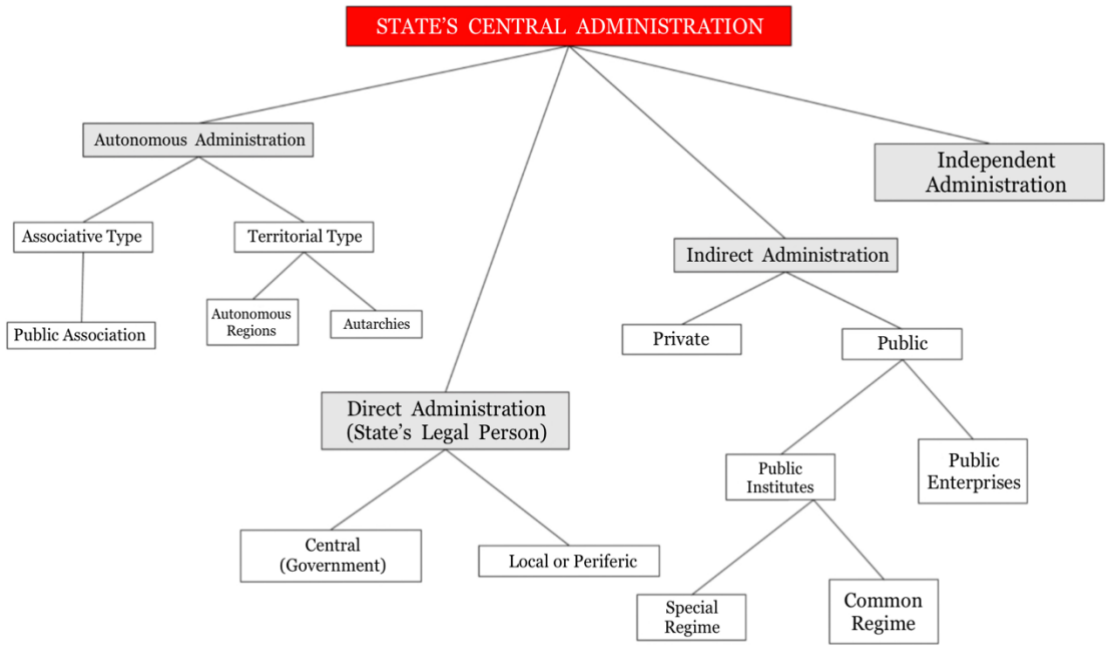
In addition, it is also necessary that there is a delegation act in itself, an act by which the competent authority grants another the capacity of performing acts regarding the subject matter.

Furthermore, there is also the question of authority, which is the set of intervention powers from the public legal person within the management of another legal person, to ensure the legality or merit of the acting.[7] Moreover, it has its goal to, under the name of the titled entity, ensure that the entitled entity is abiding by the current laws and guarantee

[5] Ibidem.
[6] Ibidem.
[7] Ibidem.

that the solutions they adopt are the most convenient and appropriate for the reaching of its purposes.

Finally, there is also the power of oversight. This is a power granted to the State or another multiple objective legal person that defines the objectives and guides singular end's public legal person's acts within their legal dependence.[8]



III. AMERICAN ADMINISTRATIVE LAW

In the American Government System, the powers are split among three branches. The legislative branch, which consists of the Senate and the House of Representatives, make new laws. The executive branch, the President and those that work under him, are responsible for executing the laws. The judicial branch, the courts, adjudicate disputes that arise under the law.

There are also administrative law "structures" that allude to designated agencies, boards, commissions, departments and other governmental institutions that have been

[8] Ibidem.

created to execute carefully defined tasks or to take responsibility for specific governmental functions.[9]

And, even though they are usually given their authority by Congress, they act as a part of the executive branch.

These institutions are created and granted powers by Congress to carry out or administer those areas of governance that would be too time-consuming and inefficient for the President, the presidential staff or Congress to manage without these structures.[10]

Furthermore, Administrative Law is the body of law that administers these structures. It includes federal laws, Constitutional provisions, executive branch directives and internal agency policies, which guide the functioning of the federal agencies.

However, Administrative Law is not necessarily applicable or limited to a specific area. It defines the authority, structure and procedures of all federal agencies.[11]

The agencies appeared in the early twentieth century due to the increasing scope and function complexity of the Federal Government. Nowadays, there are dozens of agencies within the Federal Government that oversee, regulate and administer a wide range of government functions.

Moreover, administrative agencies operate under the auspices of the executive branch and accordingly with internal procedures. However, there are also some agencies that can actually retain a certain degree of independence from the executive branch, answering directly to the President.[12]

The agency heads are generally confirmed by Congress before taking functions, yet they are mainly staffed by civil-service employees, who are selected due to their professional merit.

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[9] https://lawshelf.com/videocoursesmoduleview/administrative-law-structures-module-1-of-5 in November 21st, 2021.
[10] Ibidem.
[11] Ibidem.
[12] Ibidem.

While political appointees may only serve during the duration of the administration that appointed them, professional employees are mostly career employees within the agency they work. This is how agencies can shield their decisions from political and popular pressures, ensuring that these are made based on expertise and non-political public policy.[13]

Generally speaking, these agencies perform three types of functions. The regulatory agencies, such as the Environmental Protection Agency, serve primarily to implement laws by issuing binding rules for how laws are to be applied and to determine whether parties comply with the regulations.

Some others are created to administer federal government programs, such as the distribution of legally entitled governmental benefits, the Social Security Administration, for example, is responsible for distributing social security benefits. And finally, some are responsible for the enforcement of particular areas of law, for instance, the Bureau of Alcohol, Tobacco, Firearms and Explosives.[14]

There are also two primary operations modes that Federal agencies use: rule-making and adjudication. Rule-making reports itself to the process of issuing binding rules to implement the agency's mandate, and adjudication is where the agency employs judicial hearings to rule on claims on a case-by-case basis.

Furthermore, most agencies are authorized to carry out fact-finding investigations, while some are even responsible for issuing licenses, permits and extending legal exemptions for the areas of governance under the agency's purview.[15]

Apart from that, there are some the Congress has created that have a higher degree of autonomy marking them freer from control by the President and other parts of the executive branch.

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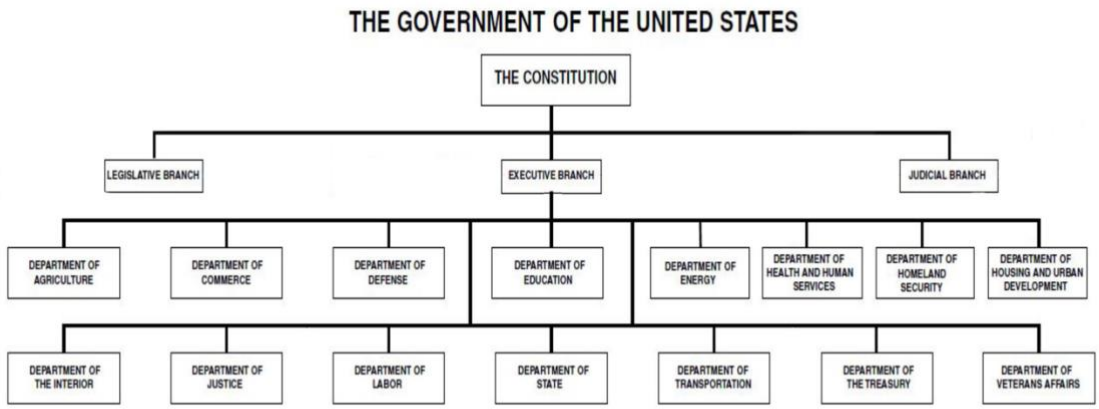
[13] Ibidem.
[14] Ibidem.
[15] Ibidem.

These are the independent agencies and are not only designed to shield the agency from political influence to a greater degree, but also usually not part of any executive department headed by a cabinet secretary.[16]

Moreover, there are also administrative agencies on the state level. State agencies usually carry out the same primary functions as federal agencies: enforcing laws, regulating businesses, and implementing state policy programs.

And even though each state has enacted its own set of laws about procedures for state agencies, many have enacted laws very similar to those that exist on the federal level.[17]



IV. PUBLIC ADMINISTRATION IN THE PHARMACEUTICAL SECTOR: INFARMED

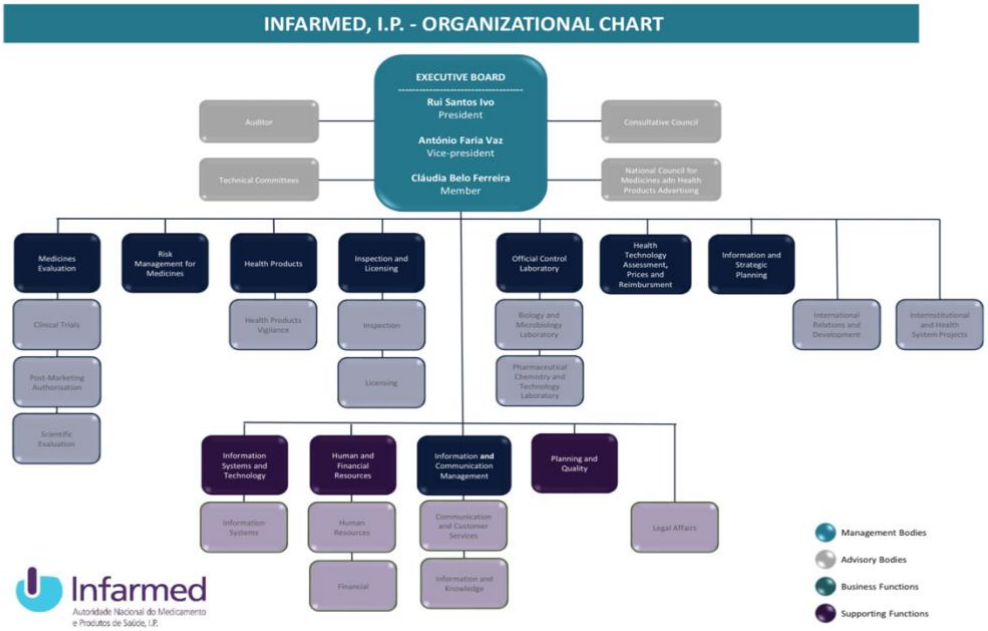
The National Drugs and Heath Products Authority (INFARMED) is a special regime public institution that, under the current law, is inserted in the State's indirect administration and, therefore, has financial and administrative autonomy, as well as it owns its own assets.

[16] Ibidem.
[17] Ibidem.

The INFARMED pursues the administrations of the Health Ministry under the oversight and tutelage of the Health Minister. It also works as a central organism with jurisdiction over all National Territory and, even though it cooperates with Autonomous Regions' organs, it does so according to its administrations.[18]

This Lisbon based public institution has as its mission to regulate and supervise the human drugs and health products sectors, according to the highest of standards regarding public health safety, and guarantees the health professionals and citizens' access to safe, efficient and quality drugs and health products.

The following organization chart reflects the structure under which the INFARMED operates.



Finally, the institute also pursues its activity in several domains at national and at European levels, such as:

- Research, evaluation and authorisation of medicines;
- Quality, safety and efficacy control of medicines;

[18] https://www.infarmed.pt/web/infarmed/infarmed in November 21st, 2021.

- Good Clinical Practices (GCP's) in clinical trials;
- Research, assessment, registration, monitoring and supervision of health products;
- Clinical research evaluation, assessment and registration of CE marked medical devices, notification of health care products and market supervision activities;
- Licensing and inspection of pharmaceutical activity;
- Licensing, auditing and inspection of manufacturers, wholesalers and pharmacies ensuring the respect for the rules applicable to each operator namely Good Manufacturing Practices (GMP's), Good Distribution Practices (GDP's) and Good Pharmacy Practices (GPP's);
- Medicines and health products quality control;
- Collecting medicines and health products samples along the whole circuit and their analytical control at Infarmed's laboratory;
- Adverse Drug Reactions monitoring through pharmacovigilance, vigilance and monitoring of the use of health products;
- Collecting and evaluating Adverse Drug Reactions or any other incidents that may occur with medical devices and any other information related with the usage of medicines and health products;
- Supervision of the evolution of the market and promotion of the rational use of medicines including generics;
- Evaluation of medicines for reimbursement purposes;
- Evaluation of pharmaco-therapeutic and pharmaco-economic studies;
- Monitoring of the access and use of medicines and health products;
- Release of information to healthcare professionals and citizens with a view to promote the safe and rational use of medicines and other health products;
- Release of information for various users through the web site of Infarmed and also through specific publications (such as the Therapeutic Handbook, the National Formulary of Medicines, the Guide of Generic Medicines, the Pharmacovigilance Bulletin, Infarmed Notícias Journal distributed to all partners);
- The Medicines Information Blue line (800 222 444);
- The Information Centre on Medicines and Health Products and the Technical and Scientific Documentation Centre;

- Development of preventive and corrective actions on the Medicines Policy under implementation.[19]

V. PUBLIC ADMINISTRATION IN THE PHARMACEUTICAL SECTOR: FDA

The Food and Drug Administration (FDA) reports itself as the first comprehensive consumer protection agency in the United States Federal Government. Ever since 1848, the Federal Government has been responsible for monitoring the safety of agricultural products through chemical analysis. This responsibility was passed to the Department of Agriculture in 1862 and later to the FDA.

The FDA is an agency within the Department of Health and Human Services. This department has its mission to enhance the health and well-being of all Americans by providing effective health and human services along with fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.[20]

Effective March 31, 2019, FDA began operational implementation of an agency reorganization.

FDA's reorganization reflects the agency's commitment to modernizing its structure, advancing on its mission and, protecting and promoting public health, so as to meet the challenges of rapid innovation across the industries regulated by the FDA.[21]

The FDA's reorganization realigns several entities across the agency to promote strategic priorities and elevates the role of the centers, offices and field forces. The following organization chart reflects the structure under which the FDA operates.

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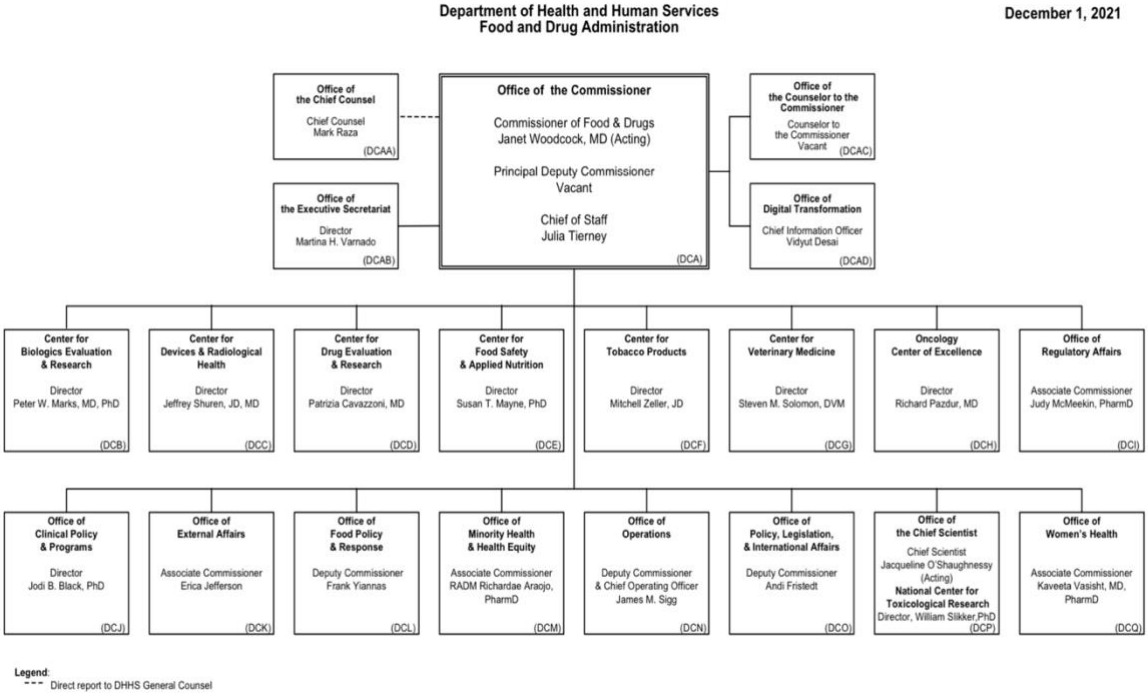
[19] Ibidem.
[20] https://www.fda.gov in November 21st, 2021.
[21] Ibidem.



The Food and Drug Administration is also responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. And to ensure the safety of the United States's food supply, cosmetics, and products that emit radiation.[22]

Moreover, FDA is responsible for regulating the manufacturing, marketing and distribution of tobacco products to protect public health and reduce tobacco use by minors. But also for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable. By enabling the public to get accurate science-based knowledge, they require to use medical products and foods to maintain and improve their health.

Finally, the FDA also plays a significant role in the Nation's counterterrorism capability. Full filing this responsibility by ensuring the security of the food supply and by fostering the development of medical products to respond to deliberate and naturally emerging public health threats.[23]

[22] Ibidem.
[23] Ibidem.

VI. BIBLIOGRAPHY AND WEBGRAPHY

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