HEALTH PROFESSIONS REGULATION IN PORTUGAL IN THE CONTEXT OF A BROADER HEALTH REGULATION FRAMEWORK

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SUMMARY

The Portuguese regulatory structure in the health area was built over decades, resulting from the dominant understanding of the different political cycles. This led to different types of regulation: one specific of the pharmaceutical area, self-regulation of the health professionals and that performed by the Health Regulatory Agency. In the area of pharmaceuticals, regulation is assured by a public institute under the indirect administration of the State and supervised by the Minister of Health that ensures access to quality, effective and safe pharmaceuticals, medical devices, cosmetic and body care products. Self-regulation that in the Portuguese context, is especially relevant in the regulation of health professions and it is performed by professional associations that have been given the responsibility of regulating the profession, as well as defining the rules of conduct and performance, among others. Thirdly, the Health Regulation Authority, created in 2002 whose duties to include overseeing health care services in regards a) to the control of the requirements for operating; b) to guaranteeing access to health care; c) protecting of the rights of users; d) ensuring the provision of quality health care; e) economic regulation; f) and promoting competition.
It is believed that regulation, in its various forms is necessary to a more equitable, socially just and responsive health system.

Key words: *Health regulation, self-regulation of the professions, Portugal*

1 INTRODUCTION

1.1 The Portuguese health system and regulation in health

In Portugal, the need for regulatory intervention in health is justified by the specificity of the health sector, in general, and by the context of the country. In Portugal, the National Health Service (NHS) is characterized by a mixed system with a combination of public and private financing and provision which comprises primary health care, hospital care and long-term care [2]. The role of the private sector has increased in the last decade, from a supply model, mainly based in specialty medical appointments, diagnostic services and medical treatments towards an investment in more differentiated health services, capable of competing in some areas with the public sector.
The private sector has experienced the emergence of large dimension corporate groups, in the hospital area and concentration of provision and significant reduction of the number of independent providers in ambulatory dialysis, clinical pathology, imagology and pathological anatomy. Also, it has a relevant role as a provider in areas where the NHS performs only as a financer, namely diagnostic and therapeutic services. The use of public-private partnerships with the opening of the first unit in 2007 added critical tension points between the management party and the contracting party, which contributed to reinforce the uncertainty degree of the PPP model, and conditioned the public perception on these partnerships [3]. The social sector also plays a relevant role in the

provision of health care services. This role was reinforced, in the last years, with the participation in the National Network of Long-term Care that led to the creation of hundreds of provision points.
The management mode in the public sector, including the use of market type mechanisms, the liberalization and opening of the market and the participation of the private sector in the provision of public services in complementarity with the public sector, brought new and complex problems.
The perception of these problems became clearer in 2002, where a new concept of a mixed system based on the complementarity between public, social and private sectors emerged. The “new” national Health System based its organization and functioning in the articulation between primary care, hospital care and long-term care networks.
It was then recognized the need to create a regulatory entity given the risks of utilization of business logic in the context of the NHS (e.g., selection of pathologies according to financial criteria, devaluation of the quality of health care and of the security of users); the need to monitor PPP and the valuation of the primary health care center. The creation of a Health Regulatory Agency (HRA) seemed therefore necessary to guarantee, in particular, universality and equity in access to health care, but also its quality [4].
We analyzed the regulation of health in general and of health professions in particular in the recent Portuguese context.

2 METHODOLOGY

Document and content analysis of legal and official documents on the creation, scope, attributions and obligations of regulatory functions of the State in terms of Health Regulations.

3 RESULTS AND CONCLUSIONS

Health regulation in Portugal assumes diverse institutional realities, with different attributions, legal capacities and areas of intervention: pharmaceutical area, self-regulation of health professions, and the Health Regulatory Agency.

3.1 Pharmaceutical area

Infarmed is a central body responsible for the regulation and supervision of pharmaceuticals, medical devices and cosmetic and body hygiene products, and ensuring access to quality, effective and safe pharmaceuticals, medical devices, cosmetic and body care products.

3.2 Self-regulation in health

Like regulation in general, professional self-regulation comprises three steps: self-regulation: definition of rules (regulations, codes of practice, etc.); self-execution: implementation, application and enforcement of the standards themselves (and applicable State standards); and self-discipline: sanctioning of infractions to the applicable norms.
Self-regulation is the most important function of the self-regulating activity of the professions, consisting of self-definition of the rules of conduct and performance of those regulated (codes of conduct are the most flamboyant example). Self-execution usually comprises the ability to apply and enforce own and allied norms, which constitute the regulatory order. This may involve, inter alia, the practice of acts provided for in norms, such as authorizations or certifications. While its primary mission may be the regulatory function, regulators often perform other tasks that have little or nothing to do with it. First, in the model of Professional Corporation, it is also up to them to represent and defend professional interests. This role covers from the general representation of the "professional category", as well as the protection of the interests of the profession vis-à-vis the State or third parties. In this role, professional corporations act as official "interest groups". Secondly, professional self-management bodies can provide services to their members, such as in service training, technical assistance, credit granting, legal advice and social protection. Thirdly, these bodies also have an official advisory role (e.g., design of normative documents).
It is easy to see that these functions, especially the first, can conflict with a correct performance of the regulatory function, by conflict of interests, between the "corporate" interest of the profession and the public interest of regulation.
The health sector has been prolific in the creation of professional associations. At present, in Portugal, the following professions are organized in a self-regulatory model: Nurses, Pharmacists, Doctors, Dentists, Psychologists and Nutritionists, and more recently, the Physiotherapists Association was approved. All of them follow a common paradigm based on the Law of

Professional Public Associations (Law no. 2/2013, of January 10th) [5]. They have the typical functions of self-regulation: establishment of rules (regulations, codes of conduct); implementation, application and enforcement of own and State standards and punishment of deviations from applicable standards; consultancy by integrating working groups, legislative or governmental commissions on topics of interest; support their members in areas related to the exercise of the profession, whether providing training, legal advice, or mediating discounts and benefits on a number of activities and services.

These professional associations have the same vices that are generically related to this model of regulation, especially with regard to the responsibility for corporatist tendencies to transform their tasks into means of restricting access to the profession and limiting the competition. There are, in fact, a number of criticisms on the difficulty (or unwillingness) of professional bodies to impose on their members restrictions that favour the general interest of consumers or transforming professional self-discipline into professional 'self-responsibility' since those being audited are simultaneously the auditors.

In conclusion, it is in the dialectic between advantages and risks of self-regulation by professional associations that its concrete fundaments must be found. Professional self-regulation is based on the tension between the collective interest of the group and the inherent public interest of regulation. Therefore, it is required that there is no incompatibility, but fundamental coincidence, between the protection of collective interests of the group or profession and the regulatory interests of the State. This principle assumes particular relevance when the background are the health professions whose exercise is directly related to the realization of constitutional rights of the users, as is the right to health.

3.3 Health Regulatory Agency

The mission of the HRA is to regulate the activity of the providers of health care services and its responsibilities include the supervision of these services with respect to a) the control of operating requirements; b) guarantee of access to health care; c) protection of the rights of the users; d) ensuring the provision of quality health care; e) economic regulation; (f) the promotion and protection of competition. Its scope of regulation includes all public, private, social and cooperative providers of healthcare services, irrespective of their legal nature, except for health professionals as mentioned earlier.

The first of its regulatory objectives is to ensure compliance with the requirements of the exercise of the activity of health care establishments, including those related to the licensing of health care services, under the law. The second objective of regulation by the HRA is to ensure compliance with the criteria for access to health care, in accordance with the Constitution and the law. A third regulatory objective is to protect the legitimate rights and interests of users. For this purpose, the HRA assesses the complaints of users and monitors its follow-up. The fourth objective of the regulatory activity of the HRA is to ensure the provision of quality health care. The achievement of this attribution resulted in the creation of the National System of Healthcare Evaluation (SINAS) which applies to hospitals and oral health providers. The fifth HRA objective is to ensure the legality and transparency of economic relations between all the agents of the system. The sixth objective of the HRA is to promote and defend competition in the open market segments, in cooperation with the Competition Authority.

Although created in an atypical context in comparison with other regulatory entities, HRA maintains the central points of regulatory activity, through the formulation, implementation and enforcement of rules directed to economic agents in the market, aimed at ensuring their balanced functioning, in accordance with determined public objectives.

In short, the Portuguese regulatory structure in the health area was built over decades, resulting from the dominant understanding of the different political cycles. This led to different types of regulation. Here, three different models were highlighted: the area of the pharmaceuticals regulated by Infarmed; the professional self-regulation exercised by Associations of Professionals; and the HRA that a) monitors operating requirements; b) guarantees access to health care; c) protects the rights of the users; d) ensures the provision of quality health care; e) is responsible for economic regulation; f) and promotes competition.

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