Interview: Eurico Castro Alves, President, Infarmed, Portugal

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Eurico Castro Alves, president of Portugal's regulatory agency Infarmed, talks about the biggest challenges facing the regulation of health products in the country today, and introduces new initiatives aimed at positioning Infarmed as a regulator of reference worldwide.

You have been president of Infarmed since 2012. What have been some of Infarmed's key milestone achievements?

Infarmed's priorities are to always maintain the capital of prestige and credibility gained over the years, provide a healthy and challenging work environment and maintain a commitment to employees without changing these values, and to keep the ability to transform and adapt to the current national or international demands.

Until now, I believe that this has been a very positive experience. The current challenges require much personal involvement, but in a general sense it has been quite rewarding.

Internally, I would highlight our contributions to the preparation and maintenance of the decisions of the Ministry of Health under the medicines policy. This has made us rise to the demands of the moment and to develop a conscious and technically robust system. The context of an external intervention imposes a difficult balance between the implementation of measures aimed at the

sustainability of the health system and the maintenance of the system itself. Thus, the activities of Infarmed reflect the constraints of this context, in particular those derived from strategic guidelines for the sector of medicine and healthcare products to achieve that goal.

Internationally, Infarmed has consolidated its position as a reference agency, in particular within the European Medicines Evaluation System and within the Official Medicines Control Laboratories of the European Union (OMCL). The technical and scientific quality and accomplished work have positioned Infarmed in third place as Reference Member State in the decentralized and mutual recognition procedures (among the 28 agencies), and in first place in the assessment of Pediatric Investigation.

The performance of the Laboratory of Infarmed, namely that among the OMCL Network of the Council of Europe, is the sixth most actively involved laboratory in the European system of post-market surveillance of mutual recognition and decentralized products, and one of the three most requested for the testing of centrally authorized biological medicines. It is also ranked fourth among European laboratories issuing the European official batch release certificates for blood products.

What are some of the most important developments in relation to your collaboration with Portuguese-speaking countries (PALOPs)?

The market of trust Infarmed has been able to maintain with these countries has paved the way for the creation of the Forum of Portuguese Speaking Medicines Regulatory Agencies (FARMED) in May 2013, an original idea of Infarmed. This connected those responsible for regulating pharmacies, medicines and health products from these countries in a network. FARMED had its first plenary meeting in November. FARMED has a vast potential for action afforded by adherence of all medicines regulatory authorities that comprise the PALOPs and that, despite the diversity of systems, national characteristics and constraints, it shows a willingness to unite around common goals of the defense of public health and protection of citizens.

FARMED is a network of regulatory medicines authorities of the Portuguese speaking countries built on a market of trust developed over the years that will act as a catalyst in the development of regulation in this sector with a view to generate synergies towards the consolidation of permanent and sustainable institutions. Access to medicines, strengthened regulation, combating falsified medicines, quality control of medicines and training of health professionals are some of the strategic areas being introduced. The heads of medicines regulatory agencies of the PALOPs took several decisions to show that this network is effectively a catalyst for the development and

consolidation of the pharmaceutical sector’s regulation in the Portuguese-speaking world through the sharing and discussion of best practices, exchange of experience, and information and technology in the area of medicines.

Approval and reimbursement of pharmaceutical products in Portugal is one of the slowest in Europe. What are the historical factors that lead to this environment?

The assessment procedures for reimbursement involve a highly complex technical scientific analysis with different procedural steps in pharmacotherapeutic and pharmacoeconomic evaluation. Many different elements of a multidisciplinary team participate, including medical experts and pharmacists. Given that these are medicines whose therapeutic added value is still not adequately demonstrated, certain processes go beyond the legally stipulated period for completion to allow for rigorous evaluation. This occurs due to many factors, including the complexity of the procedures, the need for reassessment due to submission of new technical and scientific evidence by companies, or the small number of experts and assessors available for this type of evaluation. In this context, Infarmed is introducing improvements, redesigning and simplification of procedures as well as increasing the number of experts involved.

What measures are you taking to ensure that this process can be sped up in the future?

In addition to the improvements I mentioned, I would emphasize that we are already implementing a National System for Evaluation of Health Technologies, an autonomous and integrated structure, with more resources and expertise to make a better assessment of health technologies, including medicines and medical devices.

This system will be the basis for public funding decisions for medicines and medical devices according to their cost-effectiveness. The goal is to ensure equity in national access to medicines and medical devices, making better-suited treatments available to the clinical situation of each patient, and correlating them to the resources of the national health system. After assessing the quality, safety and efficacy (performance, in the case of medical devices), the evaluation of health technologies focuses on the cost-effectiveness of medicines and medical devices, comparing new technologies with existing ones assessing its added value within the range of available alternatives. The implementation of this system will reduce the time for completion of the processes, allow more rapid introduction of innovation and provide access to health technologies more equitable among citizens.

What is your assessment of the attractiveness of the pharmaceutical market in Portugal today?

It would be impossible not to recognize the important contribution that the pharmaceutical industry has made in the efforts to reduce drug spending, namely through various agreements between the pharmaceutical industry association in Portugal and the Ministry of Health. Having a strong pharmaceutical industry is very important for national economic development and therefore we consider their contribution quite relevant. As such, Infarmed has been working closely with the national pharmaceutical industry, aiming at streamlining and simplifying our internal procedures to create a regulatory environment that favors and strengthens exports and internationalization of companies. Essentially, we have done our best to make export processes faster and to eliminate unnecessary barriers for companies to pursue their internationalization strategies.

You said in an interview that you wanted to position Infarmed as a regulator of choice for the industry and for similar agencies. In what ways can Infarmed do this regionally and globally?

Infarmed has followed a set of consistent guidelines in recent years for the adaptation to the European context, internal development and expansion of its operations. To maintain our position in the European context, Infarmed should intensify the path of specialization, positioning itself as the industry choice regulator and reference agencies in specific areas. Our choice of specialization areas/strategic interests should take into account existing expertise, national needs, and also areas of significant anticipated demand that are not widely covered in the European context, particularly new therapies and areas where Portugal can develop expertise.

To what extent do you work with other national regulatory authorities like EMA, ANVISA, or FDA, and in what capacity?

Infarmed ensures the duties of Portugal in the framework of the European Medicines System (EMS), ensuring representation and participation in the body’s evaluation activities and supervision tasks of the European Medicines Agency, the European Commission, the European Network of Authority of Medicines and Health Products, and the OMCL network. We participate in many of the working groups in charge of these activities where our merits have been recognized by our peers. Infarmed has always been actively involved in the EMS, and has had an active and informed participation. Obviously, our participation is adjusted to our human and material resources and we seek to intervene in areas where we can have differentiated contributions and add value to the system.

The same applies to collaboration with other countries such as Brazil and the PALOPs, with whom we seek bilateral and multilateral initiatives, such as FARMED to contribute to greater convergence of regulatory systems and to exchange experiences and information that will help strengthen and

promote sustainability of regulatory systems and bodies of the community of PALOPs.

What is your strategic vision for the next five years?

Infarmed set a series of interdependent objectives that are part of a medium and long-term strategy. They aim at maintaining market conformity, strengthening supervisory tools in monitoring, verification of quality and proactive risk management, strengthening communication, providing more and better information on medicines and health products to citizens, professionals and stakeholders, and focus on continuous internal improvement, streamlining processes and ensuring efficiency of resources. Additionally, we want to strengthen Infarmed's international role, through active discussion of scientific innovation and regulation, particularly in the context of the European system. We need to encourage the development of pharmaceutical products and healthcare sectors, promote the competitiveness of domestic industry through technical and scientific support and institutional collaboration, and contribute to the health system's sustainability by promoting the rational use of medicines and health products and the effective and efficient use of the resources.

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