Interview: Maria-Ceu Machado – President, INFARMED, Portugal

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03.04.2018

Tags: Portugal, INFARMED, Regulator, Healthcare, Regulatory Reform

Maria-Ceu Machado, president of INFARMED the National Authority of Medicines and Health Products, stresses the importance of healthcare restructuring and streamlining work practices in Portugal. In her first year as president, Maria and her team have brought in new rules on medicine approval times, confronted challenges in the reference pricing system and sought to improve cooperation and collaboration between government and industry.

Can you detail the milestones have you had over the past year in charge of INFARMED?

The creation of the technologies evaluation system, SINATS, in 2015 is one of the most important milestones for Portugal and has developed extensively in the past year. SINATS serves to stimulate innovation and regulate transparency on medical evaluations, and it is a tool for citizens' access to innovation: SINATS balances the sustainability of the national health system. INFARMED created the multidisciplinary commission composed of health experts, medical doctors, pharmacists and health economists.

SINATS was reviewed in September 2017, and the new evaluation deadlines were established: generics would follow a 30-day deadline, and new molecules would be brought to market in less than 180 days. Regarding the reimbursement reference price of generics homogenous groups, the amount was limited to the highest prices of a generic. These new rules apply for biosimilar prices to promote competition and the sustainability of the system. Before this change, all drugs were

submitted to a 90-day rule—which was sadly not respected. We are happy to bring this change into place to improve the healthcare system.

The Commission for the Evaluation of Health Technologies, created by SINATS, has positively impacted the reimbursement and approval for drugs because it improves lines of communication between industry and authorities. In the past, processes were less transparent, and there were too much risk and room for delay. Indeed, upon creation of the Commission, we found files existing from 2010. These extreme cases of late drug approvals distorted the average number of days for approval in Portugal and guided Portugal's reputation as a 300 day or longer approval market. Today, we approve in roughly two to three weeks; with innovative drugs, we respected the 90-day rule and given that the legislation was only introduced in September of last year, we intend to accomplish the goal of providing the Portuguese population with access to new and crucial drugs quicker than ever.

Finally, we have established specific rules relating to office and administrative operations. We now operate meetings with healthcare professionals and industry in a strict one-hour time slot, that is strictly adhered to, and we have made changes to overall office administration efficiencies concerning timings and preparations.

Portugal approved 60 innovative drugs in 2017, nine more than the previous year. What more can be done to improve the system?

The issue we confront on a daily basis is the lack of visibility of pharmaceutical companies' pipelines before they submit their dossiers. If we had eyes on these strategies, we would be able to better prepare for the arrival of these drugs. Negotiation meetings with pharmaceutical companies are a tricky affair because we are trying to buy at the best price possible, and the pharmaceutical companies are trying to sell the products that will meet the unmet needs of Portuguese patients—and we have not had sufficient time to understand the medicine. To provide the best service possible, we need to have accurate preparation and better communication in the run-up to meetings.

Concerning oncology, it is good to see several companies competing for reimbursement of one drug because that contest creates a productive environment in which we can deliver the best treatment to patients, and we make good socioeconomic progress.

Clinical trials and pharmacoeconomic assessment are an adequate way of bringing drugs to market given their inclusion and exclusion criteria. That said, we rarely see examinations that include polymedicated patients, for example, a patient that suffers from diabetes and hypertension and

depression because if we study a new medicine for diabetes, we look to target the primary concern. In the real world, however, polymedications can interact with the recuperation process. Therefore, we cannot rest on our laurels in healthcare and must continually test and focus on monitoring medicines post-commercialization, using real-world evidence. For breast cancer, Hepatitis C, cardiac failure and lysosomal diseases we intend to turn our attention to more real-world evidence-based studies.

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What more can be done to position Portugal as a clinical trial destination?

The centers located for our trials are chosen by companies whose headquarters are abroad in Switzerland, the US or Scandinavia and therefore sometimes there is a gap in knowledge and understanding of the clinical trial process that we have on the ground in Portugal. The lack of awareness is exacerbated by the lack of organization regarding clinical trial mapping. Consequently, to remedy the situation, we are mapping the country, and have created reference centers showing availability and capabilities of our testing units nationwide. We are building a national template that fits into hospitals nationwide, which will streamline hospitals' work processes for carrying out clinical trials.

Portugal has come a long way since the 90s and early 2000s when the country was ignorant of the impact and improvement that clinical trials can have in advancing healthcare. From my experience, I have noticed that clinical trials are so accurate and informative that budding young doctors learn how to research and progress their practices: the experiments are so precise and detailed that they impart useful lessons to our healthcare professionals.

What is your assessment of the current reimbursement and pricing scheme in Portugal?

Every year the reference countries for prices changes. For 2018, we have Italy, France, and Spain. Conversely, Portugal is the reference pricing point for 16 different EU countries. Curiously, this can backfire because multinational companies that want a lower price in Portugal may choose not to attempt a reduction in pricing here, for fear that it may impact their sales in up to 16 other pharmaceutical markets! The system is incredibly complex, and we must strive for dialogue and collaboration between companies and governments.

Further, it would benefit the entire system if companies were more transparent in their research practices. Nowadays, research conducted is often government or Horizon 2020 funded, and some molecules are even bought from smaller companies' research. Medicinal production, meanwhile, is

far more affordable than in previous decades. If we can bring all of this information to the table, we can have a more transparent and meaningful pricing debate.

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We see a stand-off between pharmaceutical companies who are active in marketing and doctors who are slow to take up innovations—I am in a position to comment given my long career in Pediatrics! We need to strike the right balance between the two approaches. Introducing a cap for prescriptions is an excellent way that INFARMED sees as guaranteeing that we do not prescribe too much of a drug, and accurately shares the demand load between innovative and generics. Of course, in an ideal world, we would target innovative products and always deliver the most expensive solution—but given economic constraints, we have to channel our efforts into providing a safe and effective patient-centric healthcare system that balances all elements.

How do you nurture the increasing recognition of INFARMED as a regulatory agency of reference in the EU and worldwide?

We have 86 experts at INFARMED who are members of European scientific and technical committees or working groups from the European Agency, the European Medicines Regulatory Network, and international bodies (WHO, etc.) Last February, INFARMED hosted the HMA meeting (on behalf of the Bulgarian Presidency), and we are preparing the following events in Lisbon: the fourth ministerial meeting of La Valetta Declaration and the Fourth assembly of the technical meeting in May, where Portugal assumes a leading role. And, the EAMI meeting in June for the Ibero-American medicines agencies representatives from Portugal, Spain, Andorra and 19 Central-South American countries. We are very proactive in our international operations.

What is your outlook for the healthcare sector in Portugal and the role INFARMED can play in strengthening Portugal’s healthcare system?

As a medical doctor, I am concerned with our national health system being too hospital-centric. We have experienced a recognizable evolution in primary and long-term care, but we must do more. As one of the oldest European countries, we need to have stronger primary and long-term care levels to guarantee the fulfilment of healthcare needs of older people—especially in the face of an aging population—and chronic diseases. If hospitals continue to be the focus of the central health system, the long-term sustainability is not possible nor adequate.

My motivations are to offer more pediatrician formulations because in 40 to 70 percent of medicines are off-label for children. The EMA regulation ten years ago brought in some

advancements, but more can be done to help children in healthcare.

Finally, we will continue to spread the awareness of INFARMED and its role in the Portuguese healthcare system—one of the new ways we are doing this is with an INFARMED app which informs users of new medicine approvals and releases. With our new project ‘Incluir,’ we interact with all Portuguese patient associations across the country, for which we now have 140, to understand what their priorities are, and to highlight the challenges that we face. In this way, we improve dialogue and our offering to Portuguese patients.

As a national health product authority, we will continue to perform the INFARMED mission and continue to contribute to the sustainability of our national health system.

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