Pedro Moura – Managing Director, Merck Portugal



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Pedro Moura, managing director at Merck Portugal, outlines the company's unique presence and the Portuguese affiliate's diverse portolio. He discusses the challenges around access to innovation in Portugal, where only 44 percent of the drugs approved in the European Union make it to the local market and time to reimbursement has gone up to 702 days, and explains the pivotal regulatory development that has allowed the request for reimbursement and the initiation of a patient access programme to go hand in hand, thus stepping up access.

Merck holds a unique position, spanning healthcare, life sciences, and the electronics sector. How does this diversified presence impact the company’s culture?

Our company stands out as a unique entity, operating across diverse sectors such as healthcare, life sciences, and electronics. This multifaceted presence allows us the flexibility to address various societal needs effectively. What sets us apart is our commitment to making a positive impact on society, not merely as a trend, but as an integral part of our culture. With a rich history of 355 years, we are proud to remain predominantly family-owned, fostering a strong sense of heritage and responsibility.

Most importantly, we prioritise initiatives that matter, placing a genuine emphasis on sustainability, diversity, equity, and inclusion. This commitment is not just a recent trend but a longstanding

ethos within our company. Diversity is not just a talking point for us; it is embedded in our culture. For instance, our European leadership sees a majority of women at the helm of various teams, showcasing our dedication to creating a diverse and inclusive work environment.

Our core values are anchored in curiosity, driving us to explore new frontiers and move in the right direction. This curiosity has fuelled our proactive stance, even predating the COVID-19 era. Well before the pandemic, we had already embraced remote work and adopted an omni-channel approach in our interactions with healthcare professionals (HCPs) and customers. The pandemic, in essence, accelerated a transition that we had already initiated. We had invested significantly in technology infrastructure and communication tools, ensuring that we were well-prepared for the evolving landscape, where face-to-face interactions, while crucial, coexist with a broader range of communication channels.

Taking into account that Merck has a large organisation in Spain and that some might believe the Iberian peninsula could be managed solely from one country, what is the role of the Portuguese affiliate?

The decision not to consolidate operations in a central location like Spain reflects our belief in maintaining a robust local footprint in each market. While trends in the industry have seen consolidation efforts, we value the importance of having a significant presence in each country. This approach aligns with our commitment to fostering local partnerships, such as the long-standing satellite lab in America, which has thrived for over two decades, showcasing the success of collaboration with academia and research institutions.

In essence, our organisational philosophy prioritises the unique opportunities and challenges presented by individual markets, reinforcing the idea that our commitment to global success is built upon the strength of our local connections and partnerships.

Could you provide an overview of Merck Portugal, its performance and portfolio?

When we delve into Merck Portugal’s performance, it is crucial to understand our multifaceted presence across healthcare and life sciences. While healthcare remains a cornerstone, we also hold a significant position in life sciences. From a business standpoint, my purview is healthcare, while a colleague in Spain oversees life sciences.

Our portfolio, often referred to as the core business, is robust and diversified. It comprises therapeutic options in cardiometabolic care, encompassing diabetes, hypertension, thyroids, and endocrinology. This foundation is complemented by our specialty business, delving into crucial areas such as oncology, immunology, fertility, and multiple sclerosis. In oncology, our focus extends to indications like rectal cancer, head and neck cancer, bladder cancer, and renal cancer—ultimately aimed at prolonging survival.

The three pillars guiding our efforts are creating life (fertility treatment), prolonging life (oncology), and enhancing the quality of life for chronic disease patients, particularly in multiple sclerosis. Over the years, this core business has been instrumental in shaping our market presence and driving our success.

However, it is imperative to note that we remain agile and open to exploring new opportunities. While rooted in our strengths in cardio-metabolic care, oncology, and neurology, we actively seek avenues with significant market size and high unmet needs. Our approach involves a strategic evaluation of opportunities to be either first in class or best in class.

The landscape is dynamic, and we continually assess our capabilities, skills, and legacy to discern if there are compelling opportunities beyond our established therapeutic areas. This adaptability is fundamental to our commitment to meeting the evolving needs of the market and ensuring that Merck Portugal remains at the forefront of innovation and patient-centric solutions.

Given the diverse therapeutic areas in Merck’s portfolio, how does the company approach maintaining relevance and achieving leadership in diverse market conditions?

Ensuring relevance and achieving key performance indicators in diverse market conditions is central to our approach at Merck. In the realm of cardiometabolic care, including diabetes and hypertension, Portugal, like many regions, faces challenges associated with a flattening population growth juxtaposed with a significant increase in the incidence and prevalence of these pathologies.

The surge in diabetes, pre-diabetes, and congestive heart failure is driven by two primary factors. Firstly, the lack of sufficient emphasis on prevention contributes to the rapid evolution of these conditions. Greater investments in preventive measures and early diagnosis could potentially curb the prevalence. Secondly, lifestyle habits, including dietary choices, stress levels, and a sedentary lifestyles, play a substantial role in the increasing prevalence of cardiometabolic diseases.

Our commitment to addressing these challenges involves recognising the persistent high unmet needs in cardiometabolic care. The prevalence of these conditions necessitates sustainable solutions from both financial and societal standpoints. While some drugs in the market have been integral to treatment protocols for over two decades, there is a continual need for innovation and adaptation.

Merck acknowledges the evolving landscape and remains proactive in responding to emerging trends and patient needs. Our strategies involve not only leveraging existing drugs but also exploring advancements in research and development to introduce new and more effective treatment options. Additionally, we emphasise the importance of prevention in managing these conditions.

By aligning our efforts with preventive measures, such as awareness campaigns, early diagnosis initiatives, and lifestyle interventions, we aim to contribute to a comprehensive and sustainable approach to cardiometabolic care.

How would you characterise Merck’s dialogue with the Portuguese government, considering the challenges posed by reference pricing systems?

Achieving a balance between market growth and governmental regulations, particularly in areas like cardiometabolic care, requires ongoing dialogue and collaboration. In Portugal, we have made significant progress in fostering genuine discussions with policymakers and establishing agreements that provide market predictability. The agreement between Merck, represented by APM Pharma, and the Portuguese government, renewed annually, serves as a framework, offering predictability amid the dynamic market landscape.

The reference pricing system, while not perfect, is part of this agreement and plays a role in regulating prices. It is a mechanism that provides a frame for pricing discussions, ensuring both the government and pharmaceutical companies can anticipate costs, a critical aspect for investors and the industry’s sustainability.

In this context, innovation remains key, and we recognise the importance of maintaining a balance between foundational therapies and innovative solutions. Engaging in responsible and constructive dialogue with policymakers allows us to contribute our expertise in anticipating the evolution of innovation. However, the dialogue does not end there; we also strive to include the patient perspective.

Our approach emphasises patient-directed experience and collaboration with patient associations. Rather than merely placing patients at the centre, we aim to understand their needs deeply, anticipating and prioritising unmet needs. This patient-centric approach enriches the dialogue with authorities, offering insights that go beyond regulatory discussions.

Furthermore, Merck actively contributes to this dialogue by generating extensive real-world evidence and conducting health economic evaluations. These data-driven insights help policymakers make informed decisions and enhance the overall understanding of the patient journey.

Transitioning to oncology, a field with significant complexities, can be challenging. Could you share your experiences and insights into Merck's journey in gaining approvals and navigating the oncology landscape in Portugal?

The landscape of oncology in Portugal presents its own set of challenges, particularly when it comes to first-time filings, pricing negotiations, and patient enrolments. The healthcare expenditure in Portugal has been on the rise, but the investment in pharmaceuticals, despite recent recovery, has fallen significantly compared to peers like France, Italy, and Spain.

In terms of access to innovative therapies, Portugal faces hurdles, with only 44 percent of drugs approved in the European Union making it to the market. This is below the European average and lags behind Spain, France, and Italy. The waiting time to access innovative drugs in Portugal is extended, contributing to the lower availability compared to European standards.

Navigating these challenges requires a strategic approach. Merck has focused on facts rather than abstract discussions, emphasising the need for increased investment in pharmaceuticals to improve access to innovative therapies. The company recognises the importance of maintaining a balance between healthcare expenditure and pharmaceutical investment for the benefit of patients.

In the oncology journey, addressing these hurdles involves active engagement in first-time filings, meticulous pricing negotiations, and efficient patient enrolments. While the journey may have had its complexities, Merck's commitment to providing innovative solutions in oncology remains steadfast. The company is dedicated to overcoming obstacles, contributing positively to the healthcare ecosystem in Portugal, and ensuring that patients have timely access to life-changing therapies.

In addressing the complexities of drug reimbursement and access to innovative therapies, you mentioned that the delay in bringing important drugs to the Portuguese market is a significant concern. What decision-making processes and the factors contribute to these delays?

The delay in bringing crucial drugs to the Portuguese market is indeed a pressing concern. The decision-making processes and the factors influencing prioritisation are complex. In most cases, it is not a matter of denial but rather a delay in making drugs available. The time to reimbursement has increased to 702 days, which is deemed unacceptable. This extended period creates inequalities across geographies and markets, impacting patient care.

The urgency for these drugs to enter the market is evident, and the current situation calls for a compromise between policymakers and stakeholders. Limited resources, ongoing negotiations, and the impact of the COVID-19 pandemic contribute to the complexities. It is crucial to acknowledge the sense of urgency and put effective tools in place for managing the core business drugs' sustainably.

To address these challenges, a reevaluation of the decision-making processes is necessary. Prioritising drugs based on their compelling data and real unmet needs should be a central consideration. The extended period for reimbursement negatively affects patient care, and strategies need to be devised to expedite this process without compromising the quality of decision-making. Collaborative efforts between stakeholders, innovative solutions, and a sense of urgency in responding to market needs can contribute to a more streamlined and equitable access to both foundational and innovative therapies in Portugal.

Merck was recently granted approval of new indications for its immuno-oncology drug. How significant is this milestone and what are the unique attributes that make these new indications stand out?

The approval of new indications for our immuno-oncology drug marks a significant milestone, especially given the breakthrough nature of these indications and their impact on oncology patients. The focus on key performance indicators (KPIs) and the recognition of the drug's potential benefits played a pivotal role in highlighting its importance from the outset.

However, a notable challenge emerged during the administrative process following the negotiations. While the formal administrative procedures progressed smoothly, a substantial delay occurred between the final negotiations and obtaining a ministerial sign-off. This delay is critical as the conditions agreed upon during negotiations may not accurately reflect the evolving landscape, affecting expenditure caps and subsequent developments.

How does the unique regulatory environment in Portugal impact Merck's approach to reimbursement and patient access programmes, and what strategies have been put in place to navigate the challenges in this market?

In Portugal, navigating the complex landscape of reimbursement and patient access programmes requires a nuanced strategy. Over the past six years, a pivotal development has been the simultaneous request for reimbursement and the initiation of a patient access programme when submitting data for evaluation. This innovative approach ensures that, during the roughly nine-month evaluation period, if there is no response, a guarantee is secured to supply the product to hospitals or members. In cases where reimbursement is not granted, having a patient access programme in place allows for charging for the product, provided the specific patient is approved. This dynamic approach ensures earlier access in most cases and underscores the importance of demonstrating competitive data and the absence of viable alternatives. It is a strategy tailored to the unique regulatory environment in Portugal, ensuring timely access while addressing the challenges inherent in this market.

At the beginning of the interveiw you mentioned the importance of taking into account diversity, equity, and inclusion. Can you outline Merck's approach to career development in this context?

Addressing the unique needs of our diverse workforce has been a priority, acknowledging that the one-size-fits-all approach does not suffice, especially across different locations. We understand the significance of tailoring wellness programs to respect cultural nuances, recognising that the work-life balance in one region may differ significantly from another. Our commitment is to offer solutions that genuinely meet the needs of individuals, ensuring their well-being is prioritised within the context of their specific cultural and professional environments.

In terms of professional development, we have implemented a comprehensive strategy that fosters individual accountability. Recognising that career progression is not solely about vertical promotions, we initiated a week-long professional development program. This initiative encourages colleagues to take charge of their own growth, emphasising the acquisition of diverse competencies and understanding different facets of the organisation. The goal is to empower individuals to navigate the ever-changing competitive landscape, aligning with our belief that professional development is a continuous, personalised journey rather than a linear progression.

Moreover, our approach involves instilling a sense of belonging and opportunity, making professional development a key component of our organisational culture. This commitment becomes particularly evident in our global workforce, where colleagues from Portugal and beyond have found diverse opportunities for growth, whether through regional or global responsibilities. The emphasis is on creating an environment where individuals feel not only connected but also empowered to shape their professional journey according to their aspirations and the dynamic needs of the organisation.

As you navigate the evolving landscape of Portugal's healthcare system, how do the political uncertainties, such as the caretaker government and upcoming elections, impact Merck's strategies and expectations for 2024?

The political uncertainties in Portugal, marked by the caretaker government and impending elections present challenges and opportunities for Merck in 2024. The dismissal of the Prime Minister and the scheduled elections in March raise concerns about potential delays and disruptions. We are closely monitoring the political scene, anticipating turbulence in the first half of the year. However, the assurance of the approval of the global and national health budget provides a stabilising factor.

Amidst this backdrop, the ongoing reforms in the national health system, particularly the SNSD law 61/2022, signal a significant shift in governance models, accountability, and service accessibility. The reform aims to enhance patient access to specialised services and improve the overall efficiency of the healthcare system. While the political landscape introduces uncertainties, we trust that policymakers will act responsibly, ensuring the continuity of essential reforms.

We acknowledge the need for a pact of regime, fostering medium to long-term policies that transcend political cycles. This proactive approach can mitigate the risks associated with frequent government changes, allowing for smoother transitions and sustained progress. As we engage in

constant dialogue with relevant stakeholders, we remain vigilant, adapting our strategies to align with the evolving healthcare and political landscape in Portugal.

Looking ahead to 2024, despite the challenges posed by the caretaker government and upcoming elections, Merck anticipates a successful year. The recent approval of funding for an oncology drug, coupled with Merck’s strong performance in areas such as multiple sclerosis and fertility, instills confidence. Additionally, strategies are in place to navigate the transition, including preparations for pipeline launches in late 2025 and early 2026.

However, the political landscape introduces uncertainties, and the potential for delays in ongoing health system reforms is acknowledged. The company remains engaged in constant dialogue with relevant stakeholders to align with the evolving healthcare and political landscape in Portugal.

In the face of these challenges, Merck emphasises reinforcing community engagement and diversity, equity, and inclusion initiatives. Efforts in gender diversity, exemplified by the “As One for All” initiative, aim to bring about positive change in Portugal’s corporate landscape. Additionally, Merck is committed to supporting informal caregivers, recognising their pivotal role in society.

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