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Speaking to PharmaBoardroom as Janseen is rebranding as Johnson & Johnson Innovative Medicine, managing director for Portugal, Filipa Mota e Costa, discusses the affiliate's expanded local footprint and its ranking as the number one pharmaceutical company in the country. She also explains Portugal's market access progress, including the consolidation of its Health Technology Assessment (HTA) system, and the challenges that remain with respect to access, and she outlines the growing momentum around clinical trials in the country that has led to the creation of the Agency for Clinical Research and Biomedical Innovation (AICIB).

Last time we spoke, back in 2018, you described taking over a “speedboat” at Janssen Portugal, as one of the fastest growing multinational affiliates in the country. A lot has changed over the past five years, what word would you use to describe Johnson & Johnson Innovative Medicine today and why?

While we may not always sustain the same rapid pace, the term I would choose to characterise us today is “vitality.” We remain a highly dynamic organisation, driven by a strong sense of purpose. As a key player in innovation and the advancement of healthcare practices in Portugal, we embody vitality by instilling hope in patients. Over the past five years, we have obtained approval for almost 20 new indications or products, offering crucial solutions in a challenging access

environment. This vitality extends beyond medical innovation to our role in nurturing talent. Our commitment to talent development goes beyond training programs; we are actively exporting talent, allowing individuals to either continue their growth abroad or contribute globally while based in Portugal. This approach not only benefits the individuals but also contributes to the local economy by retaining and leveraging skilled professionals. In essence, we are a vital organisation, making significant strides in medical innovation, talent development, and broader economic contributions, with much more yet to achieve.

Was this vitality a result of your existing portfolio, robust relations with the payer, the capacity of the country to absorb innovation, or something else?

The vitality observed was a result of several launches happening concurrently, creating a synergistic effect. It is noteworthy that this was not the case for all countries during that period. While we are still performing well, we are now facing significant losses of exclusivity in certain therapeutic areas. Managing these phase-outs is an integral part of the sustainability equation in the industry. Launching new products and solutions to patients is balanced with navigating the unavoidable losses of exclusivity, which is considered a routine aspect of the process. Despite challenges, we take pride in the increased impact we have made in the country, ranking as the number one pharmaceutical company for three consecutive years, impacting more patients with our solutions across the retail and hospital markets.

The expansion of our footprint and achieving the number one position in the country is more than a matter of pride. It signifies our ability to impact more patients nationwide. Managing this involves optimising opportunities within our portfolio. At its core, our success is attributed to having an innovative and value-added portfolio, a direct result of the substantial R&D investments made by Johnson & Johnson, reaching approximately USD 14 billion in one year according to public figures. However, having an innovative portfolio is just the starting point. The real challenge lies in navigating the market access process, ensuring approval, financing, and actual accessibility to patients. Our responsibility at the local level is to transform the potential of our portfolio into a tangible reality for patients. Despite the ongoing challenges in market access, particularly in Portugal, we remain committed to making a meaningful impact on patients.

What progress has been made on the country’s market access challenges over the last half decade? Did COVID push the needle in a positive way to any extent?

Over the past five years, the Health Technology Assessment (HTA) system in the country has not seen a significant inflection point. While the system was already in place, it has consolidated further during this period. One notable development is the establishment of a consolidated system where discussions around HTA processes have become more standardised and widely accepted. However, there is a recognized need for improvement in how the HTA system is utilised. The emphasis is on making the system more data-driven, aligning with its original purpose of objective analysis. Despite the existing objectivity, it is observed that the system tends to be influenced by customer orientation at times, leading to decisions that may not always prioritise the best outcome for the patient.

In essence, the market access system has progressed in terms of consolidation, but there is a call for it to become more data-driven and collaborative in its approach. The need for data-driven decision-making is underscored by the observation that in certain instances, decisions are more influenced by customer preferences rather than purely objective analysis. Additionally, there is a call for greater flexibility and collaboration in discussions, acknowledging that not all comparisons can be direct, and sometimes, indirect comparisons are necessary for a more nuanced understanding. This collaborative approach is essential for ensuring efficiency in decision-making processes and avoiding prolonged discussions that may not always serve the best interests of patients.

You mentioned the need for HTA processes to be more data focused. Currently, who is responsible for being the owners of data and how do you see digitalisation impacting not only the generation of data but also its storage and utilisation?

The responsibility for generating data primarily lies with the stakeholders involved in phase III clinical trials. In this context, the pharmaceutical industry, as the owner of the data, plays a crucial role. However, it is important to note that this data is typically public, especially when it comes to clinical trials, and its accessibility and usability are crucial for informed decision-making.

In Portugal, there is a notable challenge with data fragmentation — while there is a wealth of data, it is often scattered, not interoperable, and not easily extractable for decision-making purposes. The potential of digitalisation is seen as a significant opportunity to address this challenge. The digitalisation efforts aim to make healthcare data more accessible, interoperable, and usable. This involves creating a national view of data that goes beyond individual hospital perspectives. The goal is to build a system that allows for the seamless extraction and utilisation of valuable

information.

The EFPIA/IQVIA ‘WAIT’ Indicator shows that Portugal is one of Europe’s slowest countries in terms of access to innovation post-EMA approval. How serious of an issue is this, and what is the local industry lobbying for to redress the situation?

The issue of delayed access to innovation in Portugal is a high priority issue for us. The indicator reflects the amount of time patients have to wait for new therapies after EMA approval. This delay is identified as among the highest in Europe, and it is seen as a significant problem that needs urgent attention.

The primary factor contributing to this delay is the time taken by authorities to evaluate and grant access to new drugs. While the theoretical HTA processes might be acceptable, the actual time taken for evaluation is excessive. This delay is attributed to the need for a more data-driven approach in decision-making. Authorities are urged to understand and make decisions based on the data available rather than going through prolonged cycles of information requests.

Collaboration is highlighted as a crucial aspect of expediting the process. A more collaborative mindset, involving direct discussions and face-to-face meetings, is suggested as a means to streamline communications and avoid delays associated with lengthy email exchanges.

Another significant challenge mentioned is the creation of ceilings for every new drug. Authorities have reportedly become more stringent in setting these ceilings, leading to extended discussions and negotiations. The industry finds it challenging to accept ceilings that, in some cases, result in providing products for free until the end of the year. This aspect of market access, particularly the negotiation of ceilings, is identified as a major hurdle that adds complexity to the process.

In summary, while improvements in the agility and collaboration of the evaluation process are suggested, a key emphasis is placed on addressing the challenges associated with the negotiation of ceilings for new products. The need for a more efficient and collaborative approach to market access is crucial for ensuring timely access to innovative therapies for patients in Portugal.

In your opinion what are the most exciting developments on the horizon for Johnson & Johnson Portugal? What therapeutic areas can we expect to see being driven by Janssen’s local portfolio?

I believe the most exciting developments revolve around the dawn of precision medicine. This transformative approach to healthcare is currently making significant strides, particularly in oncology, but is expected to extend its impact across various therapeutic areas. Precision medicine involves tailoring medical treatment to the individual characteristics of each patient, allowing for more targeted and effective interventions.

Being at the forefront of this precision medicine revolution is a source of great enthusiasm for Johnson & Johnson Portugal. The potential of personalised and precision medicine to significantly enhance patient outcomes and improve quality of life is considered remarkable. The company is excited about contributing to and witnessing the advancements in this field.

The focus on precision medicine goes beyond the development of specific products; it encompasses a broader perspective that includes adapting healthcare systems, educating healthcare providers about new treatment possibilities, and fostering collaboration among various stakeholders. Biomarkers are anticipated to play an increasingly important role in this evolving landscape.

Moreover, the shift toward precision medicine is expected to imply more collaboration and data-driven decision-making. The healthcare system will need to adapt to accommodate these changes and ensure that treatments are tailored to the unique characteristics of each patient. The emphasis on data-driven decisions reflects a commitment to making healthcare more personalised, effective, and beneficial for all stakeholders involved.

Portugal is not a major player in Europe in terms of clinical trials today, with just 685 ongoing in 2021. However, it is smaller and more centralised than the fragmented neighbouring Spanish system, as well as highly digitalised, making it more suitable for post-approval RWE studies. What do you see as the necessary next steps for your country to assume a greater proportion of EU clinical studies?

I would love to see an elevation of Portugal’s role in European clinical trials. It is not only a personal goal but also a collective objective for our nation. Leading this organisation in Portugal, I am keen on leveraging our affiliation with a large corporate global entity to attract more investment into the country.

There are compelling reasons why this is beneficial for both the company and Portugal. The country presents a cost advantage compared to other European nations, boasts existing infrastructure, and

has made substantial investments. Moreover, the quality of both healthcare providers and the infrastructure is commendable. This confluence of factors positions Portugal favourably.

However, to enhance our contribution to clinical trials, we need to address certain challenges. Clinical trials operate independently of national boundaries, focusing primarily on guaranteed quality, commitment, and timely delivery. While Portugal has demonstrated quality, our shortfall lies in timing and living up to our commitments. Often, clinical trials commence with projections for enrolling a certain number of patients, but actual recruitment falls short due to organiqational and healthcare system issues.

To remedy this, healthcare providers involved in clinical trials need dedicated time, or at least a portion of their time, for patient follow-ups and identification. Sites must function as a network rather than standalone entities to accommodate patients where they are, rather than expecting them to travel to specific trial sites. This necessitates improved management and organiqation within the healthcare system.

Identifying and seizing this opportunity is imperative. Not only does it benefit the country by providing enhanced healthcare options for patients and granting healthcare providers access to cutting-edge knowledge, but it is also an economically sound decision. Clinical trials offer a unique proposition where patients receive treatment at no cost, and there is even compensation, making it a triple win situation — benefiting patients, healthcare providers, and contributing to best practices.

Do you feel that the Portuguese government considers clinical trials to be a significant opportunity, as industry players like Janssen do?

Looking at the rest of Europe, countries like Spain have made remarkable progress in embracing clinical trials as a significant opportunity. The country has strategically recognised clinical trials as a priority, with the Health Minister behind this. A cultural shift has been achieved by incorporating awareness and training on clinical trials from an early stage in physicians’ education. This recognition by authorities has allowed Spain to establish a system that nurtures the environment, demonstrating a commitment to clinical investigation. This approach has been successful in fostering a mindset where clinical trials are viewed as a crucial component of the therapeutic arsenal to treat patients.

In Portugal, there has been positive momentum in the last five years towards recognising the potential of clinical trials. An agency, AICIB, was created to spearhead clinical trials and biomedical research. The agency's purpose is to expedite research and clinical investigation in the biomedical field. While these are significant strides, the challenge lies in translating intent into action. Infrastructure and human resources are in place, but the systems need refinement. The creation of a conducive environment where clinical trials are efficiently approved and executed is the next frontier.

Various stakeholders in Portugal, including governmental bodies, recognise the importance of clinical trials and have declared them a priority. The focus now is on turning declarations into operational realities. Key factors in this process include creating efficient systems, ensuring timely approvals at both the central and hospital levels, and fostering collaboration among healthcare providers in a network structure. The existing infrastructure and skilled professionals lay a foundation, but the emphasis must shift to refining management processes.

One of the critical challenges highlighted is the time taken for approvals at both authority and hospital levels. Efforts to streamline these processes are crucial, as delays mean missed opportunities for patients. Despite advocating strongly for prioritising clinical trials, Portugal is yet to fully grasp the urgency. The call is for setting clear priorities, implementing KPIs, and instilling a sense of urgency at all levels.

Nevertheless, J&J locally has made significant strides, being recognized as one of the core countries for deploying clinical trials within the Johnson and Johnson network. Over the past five years, more than 800 patients have been included in multicenter trials in Portugal. While acknowledging this acceleration, there is a shared sentiment that there is still much ground to cover, particularly in aligning with expectations and timelines set by authorities. The advocacy for the better management and prioritisation of clinical trials continues.

Globally, Janssen rebranded to reflect its status as part of the Johnson & Johnson family of companies, with a new name, logo, and typeface. Does this shift go beyond a name change alone and does it have implications for the company's purpose and strategy?

The introduction of a new logo marks a significant moment for our organisation. It is indeed an exciting time. While it is true that the question of whether Janssen is part of Johnson & Johnson has been present for many years, and the connection was solidified starting in the 1960s, this rebranding signifies a new era. Despite the name change, our company's purpose and impact on

patients will remain unchanged. The shift to a unified Johnson & Johnson logo signals a concentrated effort in both med tech and Janssen to enhance our global impact. This transformation will be gradual, but the essence of our purpose will be emphatically accelerated.

Already, there is collaboration across sectors, but this rebranding emphasises a closer alignment. The distinct focuses of med tech and J&J Innovative Medicine in the market will continue, but with a shared goal. Our CEO envisions that, over the next decade, advancements in medicine will surpass the progress of the last 100 years. I strongly believe in this vision, considering the rapid progress in scientific understanding, coupled with the transformative power of technologies like artificial intelligence. The intersection of med tech and pharma, with their shared emphasis on healthcare, is poised to accelerate our impact on a global scale. While our purpose and commitment to patients remain steadfast, this rebranding positions us to expedite our contributions to the world.

Jennifer Taubert has set the ambitious goal of Janssen reaching USD 60 billion in sales by 2025, a USD 8 billion increase over the 2021 figure, despite some high-profile losses of exclusivity and the spinoff of its consumer healthcare branch. What are the priorities and goals that you have set for Janssen Portugal over this time?

Our primary focus in Portugal aligns with ensuring access to our innovative portfolio. This involves working towards granting Portuguese patients access to proven innovations, including but not limited to CAR-T, mental health solutions, and advancements in immunology. Over the next two to three years, our goal is not just to bring these innovations to market but to secure market access, funding, and collaboration with local stakeholders to ensure Portuguese patients benefit from these advancements.

Zooming out to a broader perspective, my vision for Portugal involves making the country an attractive destination for investment. Beyond clinical trials, which bring evident benefits in clinical, economic, and scientific dimensions, Portugal has the potential to establish itself as a hub for international service centers. These centers could serve not only the pharmaceutical industry but also extend into healthcare. The country’s advantageous factors, including lower labor costs compared to other European nations, a strategic geolocation in a favorable time zone, and proximity to the Atlantic Ocean, position Portugal as an ideal choice for global service centers.

When corporations decide where to allocate their resources, they consider the innovation-favoring environment, economic conditions, and potential for growth. It is crucial for Portugal to improve its economic and innovative landscape to compete effectively. While competition is tough, Portugal’s

strategic advantages, including its linguistic capabilities, time zone, and skilled workforce, make it a compelling location for valued and well-paid jobs in service hubs. This opportunity requires collaboration between industry players and local authorities to create an environment conducive to such endeavors.

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