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Paula Barriga, VP & GM at Novo Nordisk Portugal, discusses the high prevalence of obesity, which affects over two million people in a country where none of the available pharmacological obesity treatments are currently reimbursed and where access to innovation is slow by European standards. She explains the need for dialogue with regulatory bodies and healthcare authorities to strike a balance between reimbursement and prevention and outlines Portugal's growing importance as a clinical trials hub with Novo Nordisk investing EUR 10 million over the past year in clinical trials in the country.

Novo Nordisk stands out in the global healthcare landscape for its passionate commitment to a single focus: diabetes. How does this manifest itself in Portugal, a country with significant diabetes prevalence?

Building on the legacy of 100 years dedicated to innovating and driving change to defeat diabetes, the company's purpose has evolved to encompass a broader mission of impelling change to combat serious chronic diseases, including diabetes, obesity, cardiovascular diseases, and other serious and rare chronic diseases.

Novo Nordisk's leadership in diabetes, is indeed commendable and the progress we have seen in our science and technology has been transformative for the lives of people living with diabetes.

Still, as highlighted, diabetes continues to present significant challenges in Portugal (and in the world), with over a million people living with the condition, accounting for more than ten percent of the population.

The number of people with T2 diabetes is increasing year on year. According to data from the National Diabetes Observatory, in 2021 there were around 1.1 million Portuguese with diabetes between the ages of 20 and 79.5. This increase is related to Portugal's population ageing at a very fast pace - 2.2 million over the age of 65, and to the increase of overweight and obesity prevalence - nearly 90 percent of the people with diabetes are overweight or obese. This is a reality that threatens not only the health of current and future generations, but also the sustainability of our healthcare system, given the enormous human and economic cost of diabetes.

Despite advancements in diagnostics and treatment and substantial investments in diabetes care, patient outcomes remain less than optimal. A growing weight of diabetes in hospital admissions, the increase by almost 20 percent in in-hospital mortality and high numbers of lower limb amputation linked to diabetes persist. As indicated by the National Diabetes Observatory, the direct costs related to diabetes in 2021 were estimated to be between EUR 1.4 to 1.7 million, emphasizing the need for a comprehensive and collaborative approach to address critical questions: are we treating all patients according to the most updated evidence and guidelines available? Facing persistent national/regional asymmetries in diabetes care outcomes, are we capitalising on the learnings of the most successful? Are there different approaches to explore?

Novo Nordisk recognises that tackling diabetes requires collective efforts involving healthcare professionals and decision-makers to rethink the approach to diabetes and interlinked chronic diseases. Some ingredients for success are strengthening prevention and primary healthcare; early detection, and timely intervention to prevent complications and slow disease progression; continuity of care through more integrated and coordinated care across all levels; effective risk factor management, integrating metabolic risk factor assessment and management into routine care; and improving equity and access to care.

As a leading company committed to another century of advancing diabetes care, Novo Nordisk seeks to lead and stimulate dialogue, promoting collaboration and innovation to enhance patient outcomes and transform the landscape of chronic disease management.

How does Novo Nordisk leverage its experience from other European countries in its Portuguese strategy?

The healthcare landscape in Portugal presents its own set of challenges and we believe the experience and solutions from other countries can support us in having a more constructive and innovative dialogue with authorities and stakeholders to ensure we can overcome major barriers in the country.

Portugal is one of Europe's slowest countries in terms of access to innovation post-EMA approval (649 days). This is a very relevant and critical topic for us, as it translates in access delays to new medicines, especially in the outpatient setting. In hospitals, this is mitigated by early access programs, but they impose a significant administrative burden on hospitals and health professionals.

According to EFPIA, the Portuguese state takes a median of almost two years (649 days) to decide on the reimbursement of innovative medicines, making us the 5th country in Europe where access to innovation takes the longest. If we compare to Sweden - a country with a similar number of inhabitants to ours - it takes a median of 214 days to access innovation.

It is critical to ensure that Portuguese citizens have faster access to therapeutic innovation. For this, we need the Government to have greater ambition to invest in the existing potential of Portugal in innovation. We need to simplify the whole process of getting new drugs into Portugal, as well as reviewing the system of financing medicines, as a way of promoting access to innovation for patients and ensuring a sustainable health system.

The delay in access to innovation is a mix of political and technical issues. Both need to be improved. The political decision-makers need to speed up their involvement in the process, while at the same time providing the regulator with the means to ensure that processes are solved within the legal deadlines.

We see increased focus of our medicine's agency in enlarging its capacity with both more internal and external resources to perform the necessary assessments. There is also expectation that this process will improve with the entry into force of the EU Health Technology Assessment regulation. However, we need to acknowledge that the major barrier to reduce the time to market is the negotiation phase and the definition of reimbursement contracts with managing agreements for all new medicines and new therapeutic indications. It is critical for the current process to be optimised and even revised, but we have not seen progress so far.

Given the historical perceptions and differing opinions within the medical community, how does Novo Nordisk navigate the challenge of reshaping the narrative around obesity?

The obesity journey has been a transformative experience. And I mean this literally: for years the medical community and patients were waiting for safe and effective options to treat what we know is a serious chronic disease – one of the most prevalent in the world and with a causal link to so many other diseases, like T2 diabetes mellitus, cardiovascular disease and around 20 percent of all cancers.

After years of research, we now have safe and effective treatments for sustained weight loss, which has been a real game-changer for people living with a serious chronic disease like obesity. Additionally, these new treatments for obesity came to break the paradigm focused only on prevention, to respond directly to an unmet medical need.

Novo Nordisk takes on the responsibility of not only providing treatments, but also propelling the scientific understanding of obesity. Educating healthcare professionals (HCPs) stands as a cornerstone of our approach. We are committed to providing comprehensive knowledge about obesity and the mechanisms underlying our treatments. This involves a multifaceted strategy to ensure that HCPs are well-equipped to understand and communicate the science of obesity, ensuring readiness and creating balanced and factual expectations.

The company's commitment to education extends to addressing the broader context of obesity prevention. As leaders in the market, Novo Nordisk acknowledges that it is not just about treating obesity; it is about fostering a dialogue on prevention, lifestyle changes, and overall well-being.

While the narrative shift is ongoing, the company remains steadfast in its commitment to pushing boundaries, educating stakeholders, and making a lasting impact on how obesity is perceived, treated, and discussed.

Furthermore, our research is expanding into exploring the quality of weight loss, delving into different metabolic pathways and their implications. This not only reflects our dedication to advancing the scientific understanding of obesity but also demonstrates our commitment and responsiveness to the evolving landscape of research and development.

Could you provide insights into the current regulatory status of Novo Nordisk's new obesity treatment in Portugal? Considering the potentially significant impact on

healthcare expenditure, how does Novo Nordisk approach discussions around reimbursement?

In Portugal, none of the available obesity pharmacological treatments are reimbursed. And this is something that needs to change in order for us to address the needs of patients, especially the most vulnerable.

Recognising the high prevalence of obesity in Portugal – over two million people – we acknowledge the potential impact on the healthcare budget. As a responsible leader in this area, we are committed to finding a balanced approach that considers both the imperative of enabling better health outcomes and the need for ensuring the sustainability of the healthcare system.

We need to have open and evidence-based conversations to find the right balance, considering that, already today, obesity accounts for an estimated EUR 1.1 million in direct costs incurred by the Portuguese NHS every year. The process involves careful consideration and strategic discussions with regulatory bodies, healthcare authorities, and other stakeholders, accepting that advocating for reimbursement for a vast population may not be feasible in its entirety.

We are committed to finding balanced and sustainable ways of addressing the needs of the population – specially the underserved and vulnerable groups – while being mindful of the broader implications to the healthcare system.

Could you elaborate on the long-term use Novo Nordisk's obesity treatment? Is it envisioned as a chronic treatment, or has the approach evolved to propose a more tailored solution that might not require continuous administration for certain patient populations? How do you envision collaborating with healthcare systems to strike a balance between providing access to those in need and managing the associated challenges?

Our primary goal is to continue to better understand the biology of obesity and develop a leading portfolio of superior treatment solutions, with a clear impact on cardiovascular and other serious chronic diseases outcomes, in order to improve public health and individual wellbeing. We will innovate to address not only the magnitude of weight loss, but also weight maintenance, quality of weight loss, comorbidities, and individual treatment targets.

Discussions around the duration and continuity of treatment are ongoing, aiming to find an optimal balance that ensures efficacy, while considering the potential variations in patient requirements.

In line with this, we are exploring collaborative approaches with healthcare systems to define specific patient populations that would derive maximum benefit from the treatment. Learning from successful initiatives like the one implemented in the UK, where budgets were allocated for obesity treatments within the NHS, we see the merit in establishing clear guidelines and patient treatment pathways, prioritizing treatments for patients most in need.

An open and constructive dialogue involving all relevant stakeholders is essential to navigating the complexities of managing obesity. While we understand the challenges faced by healthcare systems, we are also committed to ensuring that obesity is recognised as a healthcare priority and people living with obesity have timely access to adequate treatment. The unmet need is huge, and for that reason we must work together to find innovative solutions that address the specific needs of patients with obesity. This collaborative effort involves open discussions, understanding the priorities and challenges faced by healthcare systems, and collectively shaping strategies that balance access to treatment with systemic financial demands.

To what extent does digitisation empower the healthcare system, and what role do you envision in facilitating the selection of suitable patients at the right time?

The role of digitalisation in healthcare is indeed crucial, and the distribution of responsibilities in leveraging this transformation involves various stakeholders. In Portugal, where different health information systems do not seamlessly operate together, we see a challenge that requires urgent action.

Novo Nordisk is actively engaging in a digital transition, particularly in diabetes management. We are part of a transformational change to a more sustainable, personalised, and effective diabetes care, catalysing the switch from disposable pens to smart and durable pens, providing peace of mind to patients and a new layer of clinical information to HCPs, resulting in better clinical outcomes and improved quality of life. Digital innovation and connectivity associated with our durable devices is also an important pillar to our environmental commitment to reduce the plastic footprint from our products.

As we look to the future, our vision includes offering more integrated treatment solutions across our therapy areas, combining our innovative medicines with devices, data, diagnostics and digital, maximising integration with the healthcare eco-system to accelerate the transition to the broader patient population, and better outcomes to the individual and society at large. In fact, in the next few years, we aspire to have digital health solutions and digital device solutions for our insulins and

GLP-1s in place, that demonstrably improve patient outcomes.

While this is a longer-term goal, we aim to deliver not only innovative medicines, but also a comprehensive, digitally driven healthcare strategy. This, however, requires collaboration with public systems and regulators. We are fully committed to participating in such collaborative efforts, believing that an integrated approach will enhance the sustainability of the healthcare system. The goal is to broaden the population served and contribute to the overall improvement of healthcare outcomes.

In light of the competition, do you anticipate any challenges arising from having a slightly higher-priced medication compared to competitors? How does Novo Nordisk plan to differentiate itself beyond pricing?

We see competition as very positive as it stimulates different players to innovate and advance better care for people living with obesity. The unmet need is huge, and we need everyone to succeed in our ambition to defeat obesity, diabetes and other serious chronic diseases.

The fact that we were first to market, leading the change towards a new paradigm in the approach to obesity, creates both an opportunity and obligation for us: an opportunity to cement our leadership position in a market with huge untapped potential; and an obligation to ensure that as many people with obesity as possible benefit from treatment.

Our primary goal is to continue to better understand the biology of obesity and develop a leading portfolio of superior treatment solutions, with a clear impact on cardiovascular and other serious chronic diseases outcomes, in order to improve public health and individual wellbeing. We will innovate to address not only the magnitude of weight loss, but also weight maintenance, quality of weight loss, comorbidities, and individual treatment targets. We will foster innovation that reduces the treatment burden, focuses on benefits beyond weight to serve different needs along the disease progression, and therapies that can be sustainably produced.

But to succeed in “defeating obesity”, we need to go beyond treatment and there we also want to daringly increase our efforts in addressing key societal challenges in areas where we have a strong position.

In obesity we are exploring bold moves of a transformative nature, innovative business models and partnerships by establishing a transformational prevention unit focused on slowing growth of obesity prevalence through prevention. Do we know how this will look? Not yet entirely, but it is

not a question of “if”, but “how” we will get there.

We are also committed to accelerating primary prevention of obesity and diabetes namely through our longstanding initiative “Cities Changing Diabetes,” a global program involving more than 40 cities, including Lisbon. The program in Portugal fosters a holistic approach, encompassing factors such as food habits, lifestyle, urban design, making a tangible impact by engaging with local communities and by making healthy choices easier, in particular for the most vulnerable. The emphasis on primary prevention aligns with Novo Nordisk’s commitment to a broader approach, recognising the multifaceted nature of chronic diseases like obesity and diabetes and their impact on people’s lives.

Can you elaborate on Novo Nordisk’s involvement in clinical trials in Portugal and the significance of the country in the global context?

Novo Nordisk’s engagement in clinical trials in Portugal is a pivotal aspect of our global research and development strategy. Portugal has proven to be a strategically important location for conducting clinical trials, with the numbers showcasing the country’s potential in contributing to our global initiatives.

We have deliberately chosen Portugal as one of the points for our clinical trials, reflecting our confidence in the country’s healthcare infrastructure, research capabilities, and the commitment of its professionals. One notable aspect is the proactive stance of the Portuguese government, which has identified the expansion of clinical trials as a key priority. This recognition aligns well with Novo Nordisk’s objectives and has created a conducive environment for us to invest significantly in research and development within Portugal. Over the past year, we have directed substantial resources, amounting to EUR 10 million, toward clinical trials in the country. This investment has enabled us to reach over 800 patients through more than 120 sites, underlining the scale of our commitment to advancing medical research in Portugal.

A distinctive element of our approach is the internalisation of the clinical team within Novo Nordisk. We believe that having a dedicated internal team fosters a deeper sense of connection and responsibility, greater synergies with other units, thus ensuring a holistic approach to drug development.

Portugal’s standing in the global clinical trials landscape is noteworthy. It ranks as the fourth country globally in terms of the number of health researchers per million inhabitants, indicating a

rich pool of talent and expertise. This makes Portugal an attractive destination for pharmaceutical companies like Novo Nordisk, seeking to conduct cutting-edge research and contribute to medical advancements. However, the country's potential still needs to be reflected in the right conditions and incentives.

According to APIFARMA, clinical trials carried out in Portugal by the pharmaceutical industry showed an increase of 43 percent between 2019 and 2022, with a direct investment of more than EUR 230 million. If already identified constraints and critical needs were overcome, companies could, on average, increase the number of clinical trials they carry out in Portugal by more than 40 percent in the near future. This is a missed opportunity that we need to tackle, building on the excellence of our researcher and centers.

Moving forward, implementing best practices from other EU countries can be the first immediate step. At the same time, we need to ensure mechanisms to facilitate the decision-making process and work towards the creation of centres of excellence for conducting clinical trials with greater autonomy, with more qualified professionals in clinical research, and with investment in a network structure, all factors capable of attracting more research projects and greater investment to Portugal.

Looking ahead, we hope that the Portuguese government will sustain its commitment to creating an environment conducive to innovation. As Novo Nordisk continues to invest in clinical trials, we envision Portugal playing an increasingly integral role in our global research initiatives, further solidifying the country's position in the realm of medical research and development.

Over the past two years, Novo Nordisk Portugal has undergone significant changes. Can you elaborate on the key initiatives and structural adjustments undertaken to enhance the organisation's well-being and efficiency? What are the top three goals or achievements you aim to accomplish in Portugal in 2024?

When I joined Novo Nordisk, my first priority was to ensure we addressed the wellbeing of the team as a fundamental pillar for our collective success. The pandemic but also other factors played into what we saw as worrying signs of stress and work life unbalance. We started measuring, understanding the root causes, addressing major concerns and the results were incredibly positive – we managed to reduce stress levels by an impressive 30 percent, and improve our work life balance by 20 percent, while maintaining high levels of engagement. This was an outstanding achievement, and we continue staying vigilant to ensure our people wellbeing always comes first.

The COVID-19 pandemic taught us valuable lessons, particularly in terms of flexibility. We are committed to maintaining the flexibility and adapting to new expectations, especially considering the evolving needs of our stakeholders. Additionally, understanding the dynamics of different generations in the workforce became crucial while integrating new perspectives and fostering a culture where everyone feeling heard and valued is a continuous priority.

Considering our evolving healthcare landscape, the interlinkage between diabetes and obesity, and our aim to foster greater synergies and efficiency in the organisation, we streamlined the organisation in two areas: a cardiometabolic unit, combining marketing and sales for diabetes and obesity, and a rare diseases unit. Enabling and supporting divisions were strengthened, ensuring we integrate fit-for-future skills and capabilities to better pursue our mission.

Looking ahead and acknowledging the significant and growing burden of chronic diseases, namely cardiometabolic, in Portugal, we see an immense opportunity to change lives at scale. It is not just about clinical hard endpoints, it is also quality of life, physical functioning, non-health related costs, productivity, mental health, just to name a few. For this, we need to reach more patients in need, ensuring we serve the right patient with the right treatment.

In 2024, we aim to secure reimbursement for obesity treatments. Recognising the challenges, we are committed to having open and balanced discussions with relevant stakeholders, in alignment with our broader vision of contributing to a healthier, equitable and more sustainable country.

A key priority will also be strengthening our digital capabilities. The emphasis on data-driven decision-making is a strategic move to navigate the evolving healthcare landscape in Portugal. We need to better understand our health professionals needs and preferences to have more relevant and personalised interaction to drive quality and scientific sound communication.

Ultimately, we aim to bend the curve of chronic diseases, like obesity and diabetes, supporting the healthcare system's sustainability and improving patient outcomes. It is an ambitious journey, but one that aligns with Novo Nordisk's commitment to making a meaningful contribute to a healthier Portugal.

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