

Interview: Gisella Dante, General Manager, Janssen Portugal



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As a company focused entirely on innovation, Janssen has remained dedicated to bringing groundbreaking new products to Portugal, ensuring access in Portugal is as stellar as anywhere else. Gisella Dante, General Manager of Janssen Portugal, outlines the affiliate's strategy to keep investments in Portugal including local partnerships.

Would you say that the environment in Portugal today is a good breeding ground for first-time general managers?

Portugal presents significant challenges, which combined with the demands of such position helps to speed up your learning and career. Many companies put first-time managers here given the size of the country. In previous roles in Brazil and Mexico, I had bigger teams and sales. Portugal is smaller in terms of business and employee dimension, but is much more complex, both economically and in all aspects of running a business. In that regard, the country represents more responsibilities. Essentially, if a general manager does well here, he or she can learn much.

Were there any specific strategies you implemented when you first arrived to tackle access and reimbursement issues?

The message is the same across the J&J organization. We are very focused on transformational innovation when bringing new products to the market. In Portugal, access to innovation is facing some delay. Therefore we try to work closely with INFARMED and the Ministry of Health to find the best ways to bring innovation to Portuguese patients. Participating in APIFARMA is also critical; we believe in the protocol, and Janssen believes this is an important tool in terms of placing everyone together to determine a solution for the Government, industry and ultimately the patients. This protocol was also the first of its kind in Portugal; no other industry has given money back to the government. Many companies had to work hard internally to make this protocol work for two consecutive years; but it represents a real partnership.

Is the innovation-focused model still important today in Portugal as it has been in the past?

This is still Janssen's sole focus. Innovation is the only way the company can make a big difference in patient's lives, as seen with the rise of life expectancy worldwide.

Of course, OTC and generics have their importance in the pharmaceutical environment, but Janssen only focuses on innovation, fulfilling unmet needs. We are not only aiming to deliver a product, but also outcomes. We want to look not only at patients, but to understand the entire context of a patient and how, as an industry, we can deliver different services that can help individuals to lead better lives.

Has that focus on innovation helped you in terms of your ability to leverage with health authorities for access and reimbursement?

When you have any kind of focus, it allows you to be more effective in terms of your resources. For Janssen Portugal, it is good to have this global positioning, which clarifies our objectives. Janssen is focused on five therapeutic areas, which may seem like a small number but on these areas we really want to make a difference. Providing transformational innovation is our DNA, and bringing patient outcomes in those five areas is core. Health authorities recognize breakthrough innovation and this is shown in accelerated approvals for e.g. at EMA level; but also at local level, entities generally distinguish innovation.

How do you demonstrate both clinical and economic value?

Clinical value is demonstrated in different steps, starting from robust clinical trials programs and their discussion on market authorization and reimbursement negotiations. The more real data we have to show to authorities, the easier that demonstration becomes. Trial information from certain

studies help as a starting point but authorities are requesting more and more local and real world data. We recognize its value and believe it will help us to show that innovation truly provides societal benefits. Presenting clinical trials results is the base for a discussion, but we will keep showing how products specifically help Portuguese patients.

How is the product portfolio of the Janssen organization represented in Portugal?

Our five therapeutics areas include oncology, immunology, infectious disease, diabetes and CNS. Every activity in Portugal is related to these five areas. The launches of J&J products in many countries have been outstanding in recent years, and our goal in Portugal is to bring these launches to Portuguese patients, who currently do not have access to such recent treatments that might be available in other countries.

Does Janssen Portugal participate in clinical trials?

Clinical trials are indeed very important for Janssen. J&J is among the top five companies investing in R&D globally. We are very proud of that and in Portugal we are currently partnering with various initiatives within the Portuguese Pharma Association aiming to promote the competitiveness of Portugal in attracting clinical trials. Clinical trials dropped by almost thirty percent in recent years in Portugal and it is important to consider that among other measures, innovation access is critical to change these numbers and bring back clinical trials to Portugal in the coming years.

In a broader context, if companies like Janssen remain committed to clinical research, could Portugal become a hub for clinical trials?

This would require significant effort from the different stakeholders. The strategic value of Clinical Research for Portugal is now being recognized by the Portuguese Government and by the National Regulatory Authorities (INFARMED). Recently, some important initiatives have been put in place, such as the launch of the National Platform for Clinical Research and INFARMED, and the Portuguese Central Ethics Committee are assuming a leading role within the EMA Voluntary Harmonization Procedure. On the other hand, there are a growing number of hospitals setting up clinical research units in order to increase their effectiveness in this field. In 2013, for the first time in years there was an inversion in the negative trend regarding the number of clinical trials approved annually. The signs are encouraging and Janssen has been fully engaged in this process.

Many of our discussions with the authorities revolve around this 30 percent decrease. If clinical trials bring better health and capital for Portugal this decrease must reverse. INFARMED is working closely with hospitals to guarantee that every center of investigation is ready and open to receive

more clinical trials.

Could you describe the partnership strategy that Janssen Portugal has with Lusomedicamenta?

Partnerships are implemented across the J&J worldwide network; Janssen is a combination of many companies. Much of our pipeline today in terms of HIV and oncology was brought to the organization through acquisitions. We have a similar strategy in Portugal in promoting partnerships with local companies. Currently, J&J has an important agreement in place with Lusomedicamenta, a Portuguese pharma manufacturing company that produces an important volume of J&J products mainly for global markets. This represents an annual investment around USD 22.5 million, and recently an additional contract was signed for the manufacturing of mebendazol tablets for developing countries, accounting for an extra investment of USD 17.5 million over the next five years. Janssen Portugal has been committed in investing in local industry, an effort that contributes to generate qualified jobs in the country.

That must place Janssen Portugal in a very competitive position amongst its competitors.

It could be but the truth is that we do it because Janssen believes in Portugal and that is the base for our decision to maintain our local partnerships. We know the health industry has an important role in this small country, as it employs many people and as an organization we try to protect that, something which is not always easy.

What is the strategic importance of Janssen Portugal in relation to the entire organization?

Portugal has an important position within Europe, and people see Portugal as a country with a team of strong commitment towards health. Given our principles of innovation, the size of a country does not matter. Every country has the same diseases, patients and problems. Our mission is to deliver unique medicine that can change lives regardless of nation.

What kind of growth can we expect to see from Janssen Portugal in the coming years?

The size of the market now is below 2007—€300 million of savings per year was a lot of money cut from the system. We truly believe that the cuts in the pharmaceutical market have reached the limit. Diseases are different now, there are different patient needs and more people are in need of innovative drugs. Private and public sector working together can build a long-term sustainable and effective health system in Portugal. Janssen will continue to play a role in that.

How would you describe your team?

For Janssen, people are very important. Janssen's credo, written 70 years ago by the company's founder, has remained unchanged and explains the company's priorities. People always come first.

This not only refers to patients but also our internal people. We work hard to have the right people, and to motivate and compensate them fairly. As a J&J leader, we can only achieve results with people. This is one of the primary reasons many individuals love this company. We respect people. When I came here in 2012, I found a very good team of motivated people that were passionate about both the company and products. Even though I was in the company for many years, I did not know much about Portugal and the team here was incredibly helpful in that regard. Everyone in Janssen Portugal takes immense pride in his or her work.

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