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Jean-Louis Anspach, general manager of Teva France, elaborates on the affiliate's transitional restructuring period as they make a turnaround effort in the face of group-wide challenges. Anspach goes on to explain what areas will be driving Teva forward while sharing his views on the French generic and biosimilar environment.

How have you adapted to take on the role of general manager over the past few months and what have been your key priorities?

When I was invited to take the position last year, Teva was in the middle of a restructuring period in France and globally due to the challenging conditions being faced by the group. Therefore, my first priority was to put in place the new organization of Teva. While part of this was downsizing, we did not want to simply cut costs; our aim was to implement an entirely new mindset and a new way of working. Although Teva is often assumed to be a pure generic player, the reality in France is that Teva has a 50/50 split between its specialty and generic business activity.

Before, these two distinct silos in the organization were not working together and had separate generic and specialty business units. As part of the restructuring, we have made a 90-degree turn and established a truly transversal team including commercial and support functions covering our entire portfolio. In this regard, my primary challenge is to shift the mindset to create an organization that can best serve our customers.

Overall, the most difficult stages of restructuring are behind us and we are moving forward with the new Teva to reach out and reengage our employees while maintaining the trust of our customers. As a newcomer to Teva, I am here to look at the glass as half full and focus on the company's 'tomorrow'. We are all excited to get moving and rebound!

How has the new global strategy of Kare Shultz, who was brought into Teva to turn the group around, been reflected on the local affiliate level?

Part of the new strategy being put in place at the group level is to become and stay the leading player in generic pharmaceuticals. Teva is already the top generic company globally, but in France, we are number four so there continues to be significant room for growth. We see opportunities to develop in the market, but not at any cost. It is important to note that profitability is a core aspect of our strategy despite being the major challenge for all companies in the generic space. The sector is rather fragile in terms of profitability and has been weakened by repeated pricing cuts and cost increases. This is a challenge the group must also overcome in other countries as we work to build cash and reduce debt.

In specialty, our objective is to manage a relatively mature portfolio with key brands like COPAXONE® in neurology while simultaneously preparing for the arrival of fremanezumab, a new biologic to treat migraine which has already gained approval by the FDA. In the US, the product is doing well with rapidly growing demand. This is a new product we are hoping to bring to Europe and to France, for which the EMA regulatory approval is expected soon. Fremanezumab will be launched in several European countries this year, however, France will come later due to its lengthy market access and reimbursement processes.

What is the strategic importance of France to Teva within Europe?

Europe is a key pillar for Teva, representing over 25 percent of the group's entire sales. These numbers have been increasing recently as other regions are facing various challenges within the industry. France is among the top four markets driving Teva's success in the region along with Germany, the UK and Italy.

France still has large growth potential in volume for generics. Moreover, in specialty, despite the hurdles of market access, once a product completes the rather lengthy process, it usually performs very well. France is quite receptive to innovation and I have historically had success when

launching innovative specialty products in this market.

What are the star products driving Teva’s portfolio?

By value, our activity is split between innovative specialty products, generics, and over-the-counter medicines accounting for 53 percent, 44 percent, and 3 percent respectively.

In our specialty portfolio, we have three primary therapeutic areas: neurology with COPAXONE®; oncology where we have a portfolio being promoted in the hospital environment; and finally, more mature products in the field of gastroenterology and respiratory. Of course, we also have our generics business which is the other side of Teva’s driving force.

How would you describe the French generics environment today and Teva’s role in the sustainability of the healthcare system?

Without the generics industry, the French healthcare system would struggle to remain sustainable in the long term. Today, generics help save EUR 3 (USD 3.4) billion in health expenditure on a yearly basis. There is however an additional one billion in saving potential if generic usage in France matched European averages. Moreover, the generic sector is an essential partner in funding innovation. Accessing groundbreaking treatments is expensive and France would like to bring innovation quicker to market.

Through our products, Teva plays a key role in supporting the Social Security from several sides. In France, we supply over 800 medicines, hold ten percent generic market share, and generate significant annual savings for the national healthcare system. Every day, Teva supplies 22,000 pharmacies in France and delivers medical products directly to 1,800 local hospitals and clinics.

As noted by the industry and French Generics Association GEMME, we see the most impactful opportunity coming from the encouragement of physicians to prescribe within the generic drug ‘repertoire’. The repertoire is the French registry of products that can be substituted directly by pharmacists. Presently, physicians are more often than not choosing to prescribe products that do not fall within this registry. While other European countries have successfully put pressure on physicians to do this via financial penalties, France, on the other hand, is looking to deliver positive reinforcements to accomplish the task.

How are generic pharmaceuticals valued by the current stakeholders in the French healthcare system?

The Macron Administration has taken several interesting initiatives which we feel are key in building future volume growth for generic products. Currently, generics only account for 37 percent of drugs sold compared to the rest of Europe averaging between 50 and 60 percent. Even countries like Germany and the UK reach 80 percent of penetration by volume. Therefore, the generic market in France represents a large, untapped saving potential that we must unlock.

Pharmacists work well to substitute what they can – up to 80 percent of substitution when possible. The government is looking to create additional incentives to drive generics usage by reducing the number of “do not substitute” prescriptions available to physicians and determining a reimbursement cap. Drugs can be reimbursed up to the price of the most expensive generic, but if a patient insists on the specialty brand, the difference will be an out-of-pocket expense.

These initiatives are a good start, but of course, the devil is in the details and we hope to collaborate with the government to put together these measures in an efficient way in order to avoid counterproductive results.

Why is France slow to embrace generic pharmaceuticals?

The French generics industry is celebrating its 20-year anniversary. When generics were first launched, France was behind schedule compared to other countries. In order to move quickly, a decision was made to go through the pharmacists with substitutions rather than the physicians. However, this caused scepticism with certain patients as they arrived at pharmacies with prescriptions from their doctors, only to then be given a different product they did not understand. This same issue is facing biosimilars today. For that reason, it is imperative to build trust around these new products, starting with physicians and expanding to all healthcare stakeholders.

However, this is history, and everyone today understands that generics are just as safe and effective as branded products. Perhaps physicians are simply accustomed to prescribing reference branded products, it is hard to say. Therefore, increasing the financial incentive to prescribe within this generic repertoire is so important because it is indeed broad enough to treat most medical conditions.

How would you describe the biosimilar environment of France today?

Through the recently announced "*Ma Santé 2022*" reform, the administration has a very aggressive ambition to reach 80 percent use of biosimilars by the end of the period to maximize savings. Biosimilar products are gaining momentum quickly in hospital settings through tender offers. In retail settings, however, the law passed to allow pharmacists to substitute with biosimilars, but the decree defining the necessary conditions has not. Still, France has taken steps to accelerate interchangeability between biologics and biosimilars, which is typically done by the physician in partnership with the patient. This is usually decided at the initiation of treatment rather than during the course of treatment.

The progression of biosimilars remains nevertheless quite positive, but to reach this goal of 80 percent use by 2022, the government will have to accelerate the construction of a clear regulatory framework.

How important are biosimilars within the portfolio offering of Teva?

We have made a strategic decision to invest in biopharmaceuticals as part of our plan for the future. These products combine our strength in generics with our knowledge of complex medicine. By making this long-term investment today, we are shaping Teva's path towards growth for the next decade.

What are the local R&D and manufacturing capabilities of the French affiliate?

In France, we participate in several global R&D projects. Since 2015, around 7,000 French patients have been involved in clinical research in five major studies run throughout 550 sites across the country.

Regarding industrial production, around 20 percent of all medicines distributed by Teva Santé are produced in France while about 80 percent come from European facilities.

What are your performance expectations of the affiliate for 2019?

Well, expectations are always relative to objectives. 2018 was a good year for Teva in that respect, both at the affiliate and global levels. In fact, last year the group exceeded its financial goals

despite going through a tough restructuring. In France, we grew in generics, held our own in specialty, and increased profitability.

In a two-year restructuring period, we are only half way through and therefore still have a demanding year ahead of us. We gave ourselves stretch goals for 2019, but we expect another positive year as we work hard to establish a solid track record of profitable growth.

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