

Daniel Roth â?? General Manager, A. Menarini GmbH

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At the end of the day, itâ??s all about peopleâ??their energy, ideas, and collaboration. People are the heart of Menariniâ??s values

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Dr Daniel Roth outlines his long-standing career with Menarini Group, its strategic evolution in Switzerland, and the broader challenges facing the healthcare industry. Dr Roth emphasizes the importance of building strong teams, the role of entrepreneurial freedom in shaping local strategies, and Switzerlandâ??s unique position in the global healthcare landscape.

What has motivated you to remain with Menarini for 17 years, and how has the company enabled you to make a lasting impact in Switzerland?

My decision to stay with Menarini for over 17 years is largely due to the peopleâ??both the Swiss team and the broader international team. More importantly, Menarini, as a mid-sized company, offered me the unique opportunity to act with entrepreneurial freedom here in Switzerland. Together with my team, I had the autonomy to shape and implement our own strategies tailored to the local market. Although achieving results was always crucial, the ability to adapt and innovate within this flexible framework made the work exciting and fulfilling. This, along with the companyâ??s strong values, has been a key factor in my long-term commitment.

How has Menarini transformed over the years, and what key milestones have shaped its growth during your tenure?

When I started with Menarini, it was a purely primary care company, with 75% of its focus dedicated to cardiovascular treatments. Over the years, we recognized the need to broaden our portfolio and explore new therapeutic areas. One of our significant successes was the introduction of an anti-allergic product, which became the market leader in a generic environment, reaching a peak in 2022. Menarini also ventured into diagnostics, specifically blood sugar monitoring, though this was a shorter-term project in Switzerland. However, the diagnostics field continued to evolve significantly in the U.S. and other countries. During the pandemic, Menarini made a major move into oncology with

the acquisition of Stemline Therapeutics, which has been a crucial step in expanding our capabilities.

Since 2014 the second generation of the Aleotti family, our owners, has taken the lead. With their clear commitment to further growth, they enabled development in new therapeutic areas. The driving force behind much of this change has been our CEO, Elcin Barker Ergun, who joined the company in 2019. She has been instrumental in pushing these initiatives forward, and her leadership has brought a new level of innovation to the company.

Today, Menarini stands as one of the world's top 35 pharmaceutical companies and one of the top 20 European firms, with over 17,000 employees – quite a big family! The speed and efficiency with which decisions are made, thanks to our direct access to leadership, is another reason why Menarini continues to drive forward so successfully.

What strategic value does Switzerland offer for Menarini's operations, given its proximity to major European markets?

Switzerland offers distinct strategic benefits, despite its small size. The country is culturally diverse, and this means that we must adapt our approaches to meet the unique needs of each region. For some projects we have a national approach, for others we have a distinct, region-specific focus to ensure effectiveness.

Moreover, Switzerland operates outside the European Union, which presents regulatory and pricing challenges that differ from those of our EU-based affiliates. While we follow some EMA (European Medicines Agency) guidelines, Switzerland's pricing structure is different, and we handle those negotiations ourselves. This local expertise, particularly in dealing with the pricing authority, the Federal Office of Public Health (FOPH), is invaluable. Rather than relying on external consultants, having an in-house team ensures that we can navigate these complexities with a deep understanding of the local regulations.

Additionally, Menarini's extensive network of partnerships across Europe makes a Swiss presence essential. A central European location like Switzerland, without representation, would weaken our regional strategy. Menarini established its Swiss affiliate relatively late, in 1996, but over the past 28 years, Switzerland has become a vital part of our operations, supporting our broader European goals.

What impact have recently passed new regulations had on Menarini's business in Switzerland?

We saw consistent growth up until 2022, particularly through the pandemic period. However, the revisions to the Health Insurance Benefits Ordinance (KLV) and the Health Insurance Ordinance (KVV) in 2024 have had a significant impact on our performance. One of the changes was the increase of the co-payment for original branded medicines from 20% to 40%, while generics remained at 10%. This change had a very positive effect on the sales of the generics. While some of our products, e.g. against hypertension or heart failure, have performed well even without heavy promotion, these changes have led to a substantial decline in sales in recent months.

How lasting are the recent legislative changes in Switzerland regarding co-payment and generic pricing? Is there flexibility, or could these regulations be reversed?

There is almost no flexibility because the pressure on the prices of the medicines is very high. It is a pity, that the benefits of these treatments are often not considered enough since they often represent the best cost-effective therapy. The Association of Pharmaceutical Companies in Switzerland (vips) and the broader pharmaceutical industry are actively engaged in discussions with policymakers, continuously informing them of the short and long-term consequences of these regulations. However, unless a major issue becomes apparent, such as a significant disruption in the supply chain, the likelihood of a change remains slim.

One potential trigger for a re-evaluation of the regulations could be a dramatic worsening of supply security, particularly in essential areas like primary care and pediatric products. vips has been focused on this issue for years and it has become an even more pressing issue since the COVID-19 pandemic. This challenge is especially notable in the antibiotics sector, where bringing new products to market is difficult due to low financial returns. Despite praise from infectious disease specialists, larger, shareholder-driven companies are often unwilling to invest in antibiotics, as the sales potential does not justify the development costs.

What is your perspective on the European Union's new R&D scheme for antibiotics, and what challenges do pharmaceutical companies face in this area?

The European Union's new R&D scheme for antibiotics is well-intended but falls short of being truly attractive. The development of an antibiotic is a costly endeavour, requiring more than 1 billion euros in investments. On the other hand, the revenues derived from these products are very low, since innovative reserve antibiotics are only used as the last option in order to minimize antimicrobial resistance (AMR). This makes it difficult for pharmaceutical companies to commit to the research and development of antibiotics, which is concerning given the growing threat of AMR.

Menarini launched the last three new antibiotics in Switzerland, from which two are classified by the WHO as "reserve" and one as a "watch" antibiotic. However, despite the clear clinical need, the financial model for antibiotics remains unsustainable. In addition, we lost almost a year by negotiating a price, despite the critical role that this drug plays in saving lives. We even arrange deliveries by taxi on weekends to ensure urgent access for patients, but such efforts make the economic viability of antibiotics even more challenging. Therefore, the companies providing these kinds of antibiotics to the market should get greater incentives for doing so. The Swiss Round Table on Antibiotics (RTA), a group of experienced specialists, is working to address these challenges on a scientific level.

What solutions are being explored in Switzerland to support antibiotic development, and how could they improve the current situation?

A promising solution under discussion is the "subscription model," sometimes referred to as the "Netflix model". Under this framework, pharmaceutical companies receive a fixed annual payment for a well-selected product, guaranteeing its availability on the market. The UK is currently running two pilot projects with payments ranging from 5 to 20 million euros per product per year. Once sales reach a certain threshold, the company doesn't receive any more payments.

In Switzerland, we are still defining the eligibility criteria for this model. A dedicated team, including representatives from the FOPH and the RTA, will determine which antibiotics qualify and what the appropriate compensation levels are. This approach could offer much-needed financial stability for companies in the antibiotic space, but more than financial incentives are required. In Switzerland, the Epidemic law is currently under partial revision. According to the FOPH, the acceptance of this new law builds the basis for the implementation of such a pull incentive system for antibiotics in Switzerland.

Given Switzerland's role in global healthcare, with institutions like WHO and Gavi based here, is the country positioning itself as a leader in addressing global health challenges, particularly in the field of antibiotics?

Indeed, Switzerland is well-positioned to take on a leadership role in global healthcare, particularly in the fight against AMR. Back in 2015, four different departments in the country came together to develop the Strategy against Antimicrobial Resistance (StAR). This strategy contributed to the relatively low levels of AMR in Switzerland compared to our neighbouring countries. In June 2024 the Federal Council approved the Once Health Action Plan 2024-2027 with six priority areas of action. In some of these, international collaborations are also defined.

Since joining the Swiss RTA in spring 2023, we have been supporting Swiss activities together with the global team from Menarini. The aim is that Switzerland, being a wealthy and capable country, should not wait for others but take the lead in shaping policies and solutions. By doing so, Switzerland can inspire other countries to join and contribute. It's a cause we believe Switzerland is ideally suited to champion, especially in the antibiotic space, where swift and decisive action is needed.

How has Menarini's primary care portfolio performed in Switzerland, and what challenges do you face in this market?

The primary care market in Switzerland has become more challenging in recent years. While our products remain reimbursed, the pricing system requires us to reduce the price of a product every three years, which places increasing pressure on our margins. Managing the same portfolio with a fixed amount of resources becomes progressively more difficult under these conditions. On a global level, we have been working to reshape our portfolio, by partnering with companies with more specialized medicine. Antibiotics are one example, diabetes and oncology are others, and very interesting products could follow in the future.

In Switzerland our portfolio remains predominantly focused on primary care, accounting for over 90% of our business. We also have a 4% share in aesthetic medicine and another 4% in the over-the-counter (OTC) area. In this market we recently launched an anti-allergic treatment. Given the lack of an established OTC infrastructure, we've partnered with an innovative player to navigate this market. While we've seen some success, entering these channels without a strong legacy has its challenges, especially when competing with larger and well-established pharmaceutical companies. But I'm convinced that qualitatively good products always have an opportunity to grow.

Globally, primary care has gained significant attention, especially post-COVID, with many governments pushing for reforms to improve the proximity between hospitals and patients. However, in Switzerland, the primary care sector hasn't seen such a strong push. The focus here is more on securing supply chains rather than reforming primary care. Some measures, such as limiting the

access of foreign doctors and allowing cross-border medical services, have been implemented, but they don't fundamentally enhance the situation in the primary care market, in particular the security of supply.

As you look to the future, how should Menarini evolve in Switzerland, particularly in terms of expanding its primary care and oncology portfolios?

Menarini has a solid foundation in both oncology and primary care, and I believe there is still room for strategic expansion. In oncology, we are well-positioned, and in primary care, we have exciting products on the horizon—not immediately, but in the near future. If the products we have in development make it to market, I am confident that we can continue to strengthen our presence in key areas such as cardiometabolic diseases and gastrointestinal disorders. After the diagnosis and the initial treatment by a specialist, the long-term follow-up is often managed by general practitioners, providing us with opportunities to expand in these therapeutic categories.

On a broader scale, it's not just about the products. Menarini is well-regarded by the medical community here, and we maintain close relationships through Continuing Medical Education (CME) initiatives and personal contacts with healthcare professionals. A unique strength of our company is the deep experience of our team—many of our employees are 15 to 25 years within the company with very long relations with their customers. As the healthcare landscape is evolving and younger doctors allow less and less access to pharmaceutical partners, the needs of the industry are changing. Therefore, we must ensure a successful adaptation of our business model for the future in order to stay attractive to our customers. Personally, I am convinced that the more the interaction between the pharmaceutical industry and its customers is digitalized, the more important a personal relationship once more becomes.

How is Menarini adapting to shifts in the healthcare environment, and what challenges are you facing with staff engagement and market access?

Our team has demonstrated remarkable adaptability, particularly given the changes in the healthcare environment over the past two decades. As mentioned, many of our representatives have been with us for a very long time, navigating shifts from an open, less complex market to today's more regulated and fragmented system. This evolution demands a higher level of flexibility and innovation, especially in how we interact with medical professionals. Previously, reps built long-term, personal relationships with individual doctors, but now we face a landscape dominated by larger proximity clinics, where doctors rotate more frequently. To remain competitive, we need to offer more than just products—we need to provide services and tools that add direct or indirect value to therapy for the patients.

We are focusing on digital solutions and new services to support doctors in their daily lives. Our staff is motivated, and we have strong backing from our headquarters to implement these changes. However, adapting to these shifts will require continuous training and engagement with our team to ensure they are equipped to meet the demands of this changing environment.

With global advancements in healthcare, especially from regions like China and Europe, how can Switzerland maintain its relevance in the industry, and what challenges does it face moving forward?

Switzerland remains well-positioned within the healthcare industry, but recent developments have made it clear that we cannot afford complacency. A notable example is when Switzerland was excluded from European medical device committees after halting communications with the European Union. This served as a wake-up call, reminding us that stability is not something we can take for granted. While Swissmedic, our regulatory authority, has made significant strides and continues to strive for first-mover status, the competitive landscape is evolving rapidly. Swissmedic's in general cautious approach in the evaluation of the submitted dossier, ensures safety but sometimes places us behind other countries in terms of speed to market.

To maintain Switzerland's positioning as an attractive country for investments from multinational companies, regulatory approval as well as pricing and reimbursement decisions must be fast and projectable.

One of the key challenges we face is the disconnect in the processes between Swissmedic and the FOPH. After the Swissmedic approval, the pricing process can take up to a year, far beyond the expected two-month timeline. In addition, the outcome of the price negotiations is often difficult to predict. As a consequence, Swiss affiliates lose priority within the internal rankings of multinational companies. This can then lead to delayed launches and in the worst-case scenario of no launch at all. Switzerland must stay engaged and proactive if we are to maintain our leadership in healthcare and avoid falling behind in this rapidly advancing global industry.

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