Ricardo Werner Marek – President Europe & Canada, Takeda

Europe is central not just as a market but as a hub for pioneering advancements in healthcare

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Europe and Canada (EUCAN) have an essential role in Takeda's global mission to advance healthcare innovation. Ricardo Marek, President of Takeda's EUCAN division, discusses the operational and regulatory challenges, the importance of Switzerland as a strategic base, and Takeda's post-Shire acquisition growth strategy.

How does the Europe & Canada (EUCAN) division contribute to Takeda's global strategy, and what experiences have shaped your leadership in this role?

The EUCAN division, spanning 37 countries, is integral to Takeda's mission, as it focuses on delivering innovative medicines and building a sustainable business across Europe and Canada. My journey with Takeda began 14 years ago in Brazil, where I initially served as CFO, helping to drive growth through strategic acquisitions. A year later, I became General Manager for Takeda Brazil, overseeing initiatives that maximized growth in this vital market. This experience led to my role as Head of Latin America, where I managed operations from Mexico to Argentina, with Brazil as a cornerstone due to its substantial pharmaceutical market.

In 2017, I transitioned to Singapore as President of Emerging Markets, taking on the significant task of integrating Shire. This involved aligning new talent and strategy while focusing on specialized therapeutic areas like rare diseases, oncology, and neuroscience. A key component of this role was divesting non-core assets, particularly primary care and over-the-counter products, allowing Takeda to sharpen its focus on these priority areas. Additionally, I championed efforts to improve access to medicines in low-income regions, especially in Africa, a mission that remains close to my heart and thanks to the hard work and dedication of our teams, we saw an impressive jump in the global ATM Index climbing 10 places.

Relocating to Switzerland in 2020, I took on the EUCAN leadership with a commitment to advancing innovative treatments while enhancing access to medicines throughout Europe. This is particularly crucial in light of the evolving EU pharmaceutical regulations, which present unique challenges.

For me, working at Takeda is all about the people, and it always has been for me. Our people are our greatest asset and as the head of this dynamic region I'm dedicated to fostering a supportive environment for our teams, emphasizing well-being and career growth. This includes how we work flexibly, ensuring our colleagues can shape their week according to both professional and personal commitments. It's great to see strong collaboration in the office, but it's also important to respect that many people enjoy the different balance that working from home brings. I am really proud of our approach to hybrid working and it seems colleagues appreciate it also.

And as we know technology and data are reshaping our industry, my role involves preparing our people to thrive in this future landscape. Takeda is committed to innovation and employee development, this means we create learning and career growth opportunities for our employees supported through technology.

What is Europe's strategic role within Takeda's global operations, and how do you address the unique challenges and opportunities in this region?

Europe, along with Canada, is a vital part of Takeda's global strategy, contributing a significant portion of global revenue and generating substantial cash flow for the organization. This approach ensures that our treatments are accessible across a wide range of markets, maintaining both affordability and market reach.

Takeda's global operations are organized into five main areas: the U.S., Japan, China, Europe with Canada, and an additional group known as Growth & Emerging Markets encompassing close to 80 countries. Within this framework, Europe's value goes beyond financial contributions; it is central to our ability to bring innovative medicines to patients swiftly. With recent changes in EU pharmaceutical regulations, we can now launch new treatments in Europe within a year of U.S. FDA approval, a remarkable acceleration compared to other regions where launches may face delays of up to five years.

Europe is also a key region for clinical research, hosting trials at every phase. Countries like Germany, France, Italy, the UK, and Spain—where efforts have been especially impressive—are indispensable to our research endeavors. Our teams at the regional and local level actively engage with policymakers and collaborate closely with organizations like the European Federation of Pharmaceutical Industries and Associations (EFPIA), of which I am a Board Member, to encourage innovation in Europe. Europe's role is therefore not only as a revenue generator but as a region that fosters cutting-edge advancements in healthcare.

What is your view on the upcoming EU pharmaceutical regulations, and how does Takeda address both the challenges and opportunities they bring?

This offers a rare and significant opportunity to reshape the regulatory landscape in Europe, marking the first major legislative update in two decades. This reform is a complex, multi-stakeholder effort involving members of the European Parliament (MEPs) and other policymakers, many of whom may not fully understand the pharmaceutical industry's intricacies—such as the realities of unmet medical needs, the importance of rare disease treatments, and the lengthy process of developing innovative medicines. Industry professionals, including those at Takeda and within the European Federation of Pharmaceutical Industries and Associations (EFPIA), play a crucial role in clarifying these complexities and advocating for policies that support both innovation and patient access.

Over the past years, Takeda and EFPIA members have engaged extensively with health ministers across Europe, explaining the significance of this regulatory package. With a new EU Parliament and Commission now in office, the focus includes bringing these new officials up to speed on the value of fostering a supportive environment for pharmaceutical innovation. This is vital yet time-consuming work, given the need to influence perspectives and shape policies that can impact patient outcomes across the continent. One major concern for Takeda, as well as for the broader industry, is the proposed reduction in standard Regulatory Data Protection (RDP) from eight to six years. Such a reduction could dissuade companies from conducting clinical trials in Europe, leading to delays in bringing new treatments to European patients. Developing an innovative medicine is often a decade-long, resource-intensive process, and maintaining adequate incentives for this work is essential for timely access to breakthrough therapies.

As a company, we continuously evaluate the potential impact of these regulations, especially given that the Europe and Canada (EUCAN) region represents a significant part of our global revenue. We believe that a collaborative, multi-stakeholder approach is necessary, and EFPIA has been vocal in advocating for regulatory adjustments to keep Europe competitive in research and development (R&D). For instance, the recent Draghi Report on Europe's Competitiveness has a dedicated section on healthcare, here it recommends eight reforms that align with Takeda's longstanding advocacy. If adopted, these reforms could significantly boost the speed of innovation and number of clinical trials within Europe, countering the current trend of increased R&D investment shifting to the U.S. and China due to Europe's more demanding regulatory environment.

To understand the importance of these reforms further, I recommend reviewing EFPIA's analysis of the R&D investment gap between Europe and the U.S., available on their website. This analysis highlights how essential regulatory reform is for sustaining Europe's role as a global leader in pharmaceutical innovation.

How does Takeda view Europe's potential as a centre for R&D, and in what ways can universal healthcare systems support innovation, especially for rare diseases?

Europe holds significant potential as a research and development hub, and at Takeda, we firmly believe in the region's scientific talent and expertise. Knowledge and skill are not exclusive to the U.S. or China; Europe has a long-standing legacy in innovation. The key to revitalizing Europe's R&D ecosystem lies in fostering collaboration among academic institutions, pharmaceutical companies, and government bodies. This collaboration must be supported by EU legislation that actively incentivizes investment. Capital flows toward environments that offer efficient and supportive regulatory frameworks, whereas excessive bureaucracy tends to push investments to regions with more streamlined processes.

The stability provided by Europe's universal healthcare systems further enhances its appeal as a site for innovation. These systems allow for consistent, long-term planning, which is essential when addressing complex areas such as rare diseases. Within this domain, Europe's governments and the European Medicines Agency (EMA) recognize the pressing need to improve care and access for patients with rare diseases. With over 7,000 rare diseases identified globally, no single company can address them all; at Takeda, we concentrate on specific diseases, working alongside organizations like EURORDIS (the European Organization for Rare Diseases) to extend our reach and impact.

One of the primary barriers to effective rare disease treatment is the challenge of early diagnosis. Strengthening diagnostic infrastructure across Europe would not only improve patient outcomes but also lessen the societal and familial impacts of delayed diagnoses. Countries such as Germany have implemented orphan drug regulations to address these needs, creating frameworks that support the development of rare disease treatments. Moving forward, it is critical for European nations to establish dedicated platforms for rare diseases within their healthcare systems, going beyond EMA guidelines to meet specific national requirements. For instance, Sweden’s establishment of a rare diseases healthcare platform in 2022 highlights the importance of a united, multi-stakeholder approach.

By creating these frameworks, Europe can build a cohesive, continent-wide strategy for rare disease management that aligns legislative, clinical, and societal priorities. Such a collaborative approach is essential to addressing the complex and diverse needs within rare disease care and strengthening Europe’s position as a leader in global healthcare innovation.

What are the main challenges in achieving early diagnosis for rare diseases, and how does Takeda help to address these complexities?

A comprehensive solution for the early diagnosis of rare diseases is complex and requires a collaborative, multi-stakeholder approach that goes beyond the capabilities of any single organization, including Takeda. Early diagnosis often begins within the family, as parents are typically the first to notice unusual symptoms in children—a process that can be especially prolonged with conditions like Huntington’s disease, where symptoms may take years to fully manifest. However, once a family seeks help, they face the significant challenge of finding specialists knowledgeable in rare diseases, of which there are over 7,000 types.

Even after reaching a specialist, diagnosis can take months, sometimes extending up to a year. This highlights the critical need for effective communication and education to support families navigating this journey. At Takeda, we aim to facilitate this process through partnerships with the European Federation of Pharmaceutical Industries and Associations (EFPIA), participation in Rare Diseases Summits, and collaboration with EURORDIS, the European Organization for Rare Diseases. Our efforts focus on raising awareness, disseminating information, and helping society understand the profound impact of rare diseases.

Ultimately, diagnosing rare diseases requires a multifaceted approach involving healthcare providers, governments, and advocacy organizations, all working together to improve access to information, support for families, and availability of specialized care. Through collaboration, we can build an ecosystem where families are empowered, specialists are accessible, and diagnoses are achieved more swiftly and accurately.

How does Takeda drive growth and maximize access to its rare disease portfolio in Europe, and what strategies support the development of both existing and upcoming products?

At Takeda, our approach to developing new therapies is global in scope, aiming to address unmet medical needs across diverse regions rather than focusing solely on Europe. With a presence in over 80 countries, our research pipeline reflects this commitment, with around 60% of our designations focusing on orphan drugs for rare diseases. Our strategy in rare diseases is guided by targeted capital allocation and the careful selection of therapeutic areas, ensuring that our resources are directed where they are most impactful.

With our 70-plus year legacy in rare diseases and deep research expertise, we strategically expand reach of some or our established rare disease treatments by focusing on regions where certain conditions remain underdiagnosed. This allows us to extend the life cycle and impact of these treatments, enhancing patient access where it is most needed. Also in our more established treatments, we are conducting additional clinical trials, reinforcing our commitment to delivering clear, evidence-based insights to patients and healthcare professionals

Additionally, our “growth and launch brands” within the global portfolio division are pivotal in sustaining our growth. These key brands currently account for nearly 50% of Takeda’s global revenue and about 48% of revenue in Europe, with double-digit growth. As we introduce new therapies, these established brands continue to drive momentum. Our CEO, Christophe Weber, and our executive team routinely review and refine our strategy to ensure that our product launches and life cycle management align with the latest market demands and patient needs. This adaptive approach empowers Takeda to support both legacy and emerging treatments, strengthening our global presence and ensuring wider patient access to innovative therapies.

How does Takeda view the impact of the new EU pharmaceutical legislation on product launches and reimbursement across Europe, considering the diversity of healthcare systems?

The proposal by the European Commission on new EU pharmaceutical legislation marks a substantial shift, requiring that newly approved medicines be launched across all 27 EU member states within two to three years of marketing authorization. This regulation is aimed at ensuring timely access to innovative treatments for patients throughout Europe. However, the diversity of economic conditions and healthcare funding systems across member states presents significant operational challenges, particularly in negotiating reimbursement, which occurs at the national level. Each country has distinct GDP levels and healthcare budget capacities, making it necessary to tailor approaches to align with local circumstances.

For Takeda, and the industry as a whole, this legislation requires swift and synchronized action across a wide array of markets, each with unique pricing and reimbursement frameworks. Reimbursement negotiations can vary widely in duration, from six months to two years or more, creating potential bottlenecks in regions with extensive regulatory demands. This calls for adaptability not only from pharmaceutical companies but also from national authorities. Through the European Federation of Pharmaceutical Industries and Associations (EFPIA), Takeda actively engages with policymakers to advocate for flexibility that considers both EU-wide access goals and the specific financial constraints of each country.

The establishment of a centralized European Network for Health Technology Assessment (EUnetHTA) also plays a critical role in this framework. Some member states, such as France and Germany, have robust Health Technology Assessment (HTA) systems, while others do not, leading to disparities in evaluation capabilities. Ideally, EUnetHTA will create a unified assessment framework, enhancing efficiency while allowing countries with established HTA bodies to maintain a degree of independence. This centralized approach aims to create a “win-win” scenario, where both the EU and individual countries benefit from streamlined processes.

For this system to function effectively, Europe must find a balance between centralized HTA standards and the distinct needs of each member state. At Takeda, we view this as an opportunity for collaboration that respects national autonomy while advancing EU-wide access to innovation. A well-implemented framework can enhance patient access to cutting-edge therapies across Europe, strengthening the continent’s position as a leader in healthcare innovation.

What strategic advantages does Takeda gain from its European base in Switzerland, and what direction will the company pursue following the Shire acquisition?

Switzerland offers Takeda significant strategic advantages as our European base, despite being outside the European Union. Chief among these is access to a highly skilled talent pool. Switzerland’s stability, pro-business environment, and outstanding universities attract top talent, and many professionals at Takeda choose to work here to deepen their expertise and advance their careers. This has helped Switzerland become a hub for our multi-country operations in Europe.

Switzerland’s central location within Europe also enables efficient connectivity, allowing our team to travel easily to key cities like Berlin, Madrid, and Paris, often within a single day. The favorable time zone is another benefit, facilitating seamless communication with our colleagues in Asia—who are six hours ahead—and in the U.S.—who are six hours behind. This allows for real-time collaboration with global teams, optimizing productivity. Additionally, Switzerland’s tax advantages across different cantons create an attractive financial environment for pharmaceutical companies like Takeda. Our manufacturing site in Neuchâtel, which produces critical products distributed across Europe and worldwide, further strengthens our network.

In terms of growth, Takeda does not anticipate another acquisition on the scale of Shire, which was transformative, positioning us among the top ten global pharmaceutical companies. This achievement fulfilled a long-term strategic goal. While large acquisitions are no longer in focus, we continue to pursue targeted “bolt-on” acquisitions that align with our core therapeutic areas. For instance, last year, we acquired a portfolio from Nimbus Therapeutics, focused on treatments for psoriasis and psoriatic arthritis. Furthermore, we have secured the license for an innovative oncology drug from HUTCHMED, a leading Chinese biopharmaceutical company. These selective acquisitions enrich our portfolio in critical therapeutic areas, allowing Takeda to continue expanding strategically and sustainably, strengthening our position as a leader in the global pharmaceutical landscape.

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