EXECUTIVE
FORECAST

Germany
2025

This new edition captures how the landscape has shifted in the face of political change, strategic reforms, and global uncertainty.

Innovation Forward

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Executive Forecast: Germany 2025: Innovation Forward

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Credits: Executive Publisher: Ines Gray, Managing Editor: Hannah Kreher, Commercial Coordinator: Paula Santamarina Aguirre, Editorial Collaborator: Josef Gasse-Coope

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Contibutors

"Industry leaders aligned in driving sustainable health innovation across the world."

Rüdiger Schulze
Ultragenyx
Vice President & General Manager DACH

Manfred Heinzer
Amgen Germany
Vice President & General Manager

Dr. Daniel Steiners
Roche Pharma AG
General Manager, Germany -

Christiane von der Eltz
BERLIN-CHEMIE Menarini
General Manager & Executive Board Member

Marion Bock
IBSA
General Manager, Germany

Wouter Peperstraete
Hologic DACH
General Manager DACH -

Dr. Elmar Kroth
Pharma Deutschland
Deputy General Manager

Marc Schreiner
Berlin Hospital Association
Chair of the Committee EU/ International Affairs, German Hospital Federation

Roberto Godoy
Beckman Coulter Diagnostics
Managing Director North and Central Europe, Portugal and European Distribution

Michael Kickuth
Recordati Rare Diseases
General Manager DACH

Dr. Frank Wartenberg
IQVIA
President Central Europe

Dr. Stefan Koch
Klosterfrau-Gruppe
CEO

Andreas Burkhardt
SVP General Manager Teva Germany & Chair Pro Generika

Johannes Inama
Angelini Pharma
General Manager Germany

Julia von Gablenz
Zoetis
Regional President for Europe and the Middle East

Prof. Dr. Karl Broich
BfArM
President

Thomas Weigold
Sandoz
Country President Germany

Dr. Richard Ammer
MEDICE
CEO

Mikko Vasama
Philips Health Systems
Managing Director DACH

Christian Wieszner
CSL Behring
VP DACH Cluster

Urs Voegeli
J&J Innovative Medicine
Managing Director

Josip Mestrovic
Zentiva
General Manager Germany & Switzerland

Andrea Passalacqua
Alexion
Vice President and General Manager Germany

Jan Kengelbach
Aenova Group
CEO

Alexandra Bishop
AstraZeneca
Country President Germany

Luca Valsasina
VitalAire
General Manager Germany and Romania

Rabea Knorr
BDI
Head of Department Health Industry

Achim Hartig
GTAI & OECD
Managing Director of GTAI and Chair at the OECD IPA

Prof. Dr. Ralf Huss
BioM Biotech Cluster
Managing Director

Ulrich Hoppe
German British Chamber of Industry and Commerce AHK,UK, Director General

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Opening words

Two years after the launch of our first edition, Executive Forecast returns to Germany with a second look at one of Europe's most influential healthcare systems. This new edition captures how the landscape has shifted in the face of political change, strategic reforms, and global uncertainty.

Since our last report, Germany has undergone a significant political transition. The "traffic light" coalition, an alliance of the Social Democrats, the Greens, and the Free Democrats, collapsed after three years, following prolonged disputes over the national budget. Early elections were held in February 2025, resulting in a win for the Christian Democratic Union and its Bavarian sister party, the Christian Social Union. In a new coalition with the Social Democrats, and with Friedrich Merz as chancellor, the new government is navigating a critical moment for the country's economy and public services, including healthcare.

In the pharmaceutical sector, there has been a significant evolution. When we last spoke to leaders in the field, there was widespread concern over cost-containment measures proposed in the Health Ministery's financial stabilization act. At the start of 2024, however, the Pharma National Strategy was launched, marking a renewed effort to strengthen Germany's role in pharmaceutical research, development, and manufacturing. The first concrete step, the Medical Research Act, introduced a key change: pharmaceutical companies can now keep reimbursement prices confidential, helping preserve competitiveness and support long-term innovation.

Meanwhile, global supply chain disruptions and changing trade dynamics have pushed Europe toward greater independence. Germany is at the center of this shift, with a renewed focus on reinforcing its internal market and expanding strategic partnerships. As the international landscape becomes more fragmented, Germany's stability and scientific strength continue to make it a critical anchor for healthcare development in the region.

We're excited to return to the heart of Europe and explore why Germany, despite globally growing challenges, remains a powerful force in shaping the future of healthcare. This report brings together the most important voices across the sector to deliver a clear message: keeping health high on the agenda is non-negotiable.

"The health industry is a key pillar of stability and growth. It is a major driver of jobs, innovation, and resilience. In today's world, national security is no longer just about defense or energy. We need to have a strong, innovative health industry capable of responding to future crises. Healthcare is not only about treating patients — it is about building the foundation for a stable and sovereign economy." **Rabea Knorr,** Head Of Department Health Industry, BDI, Germany

Chapter 1

Germany's Evolving Landscape

"For Germany to reclaim this leadership, it hinges on several factors: fostering an environment conducive to foundational research, encouraging innovation, and ensuring universities and institutions can develop new products without immediately transferring them abroad. The healthcare sector has become a critical focus for the government. I sense a strong commitment to creating an environment that drives innovation and positions the healthcare sector as a growth area." **Dr. Stefan Koch**, *CEO, Klosterfrau AG, Germany*

Changing Frameworks: A Turning Point for Innovation and Market Confidence

"We need a clear plan to ensure sustainable healthcare financing, which also ties into the frameworks: what we reward, protect, and how we fund innovation for the future. Tackling bureaucracy and complexity, and boosting digitalization will help." Alexandra Bishop, Country President, AstraZeneca, Germany

In early 2024, Germany took a major step forward in rethinking its approach to healthcare and pharmaceutical development. With the rollout of the first phase of its Pharma National Strategy, the country set out to reclaim its position as a global leader in life sciences by making it easier to innovate, invest, and collaborate in the health sector.

The Medical Research Act: Strengthening Innovation & Research Capacities

A central part of this effort is the Medical Research Act, which introduced one of the most significant updates to the country's drug pricing system in over a decade. Since 2011, Germany's AMNOG process — short for *Arzneimittelmarktneuordnungsgesetz*, or the Pharmaceutical Market Restructuring Act — has required new medicines to go through a benefit assessment and a public price negotiation. While this brought transparency and cost control, it also discouraged some pharmaceutical companies from launching in Germany, fearing the impact on global price benchmarks.

Now, for the first time, manufacturers can request that the final negotiated reimbursement prices stay confidential for the duration of the product's data exclusivity period. In exchange, companies agree to a rebate and must demonstrate that part of their research or development is happening in Germany. This shift is designed to keep innovation flowing into the market while protecting commercial interests and ensuring national value.

Another important change is the effort to attract more clinical research back to Germany. If at least five percent of a drug's clinical trial participants are enrolled in Germany, manufacturers can benefit from greater flexibility during price discussions. The strategy also simplifies the clinical trial approval process. A new Federal Ethics Committee and more centralized coordination have dramatically reduced approval times, making it easier and faster to run studies and bring therapies to patients.

Prof. Dr. Karl Broich, President, BfArM, elaborates on the industry's response to the requirements set forth by the Medical Research Act: *"BfArM has established a dedicated Department for Innovation Management. This department houses an Innovation Office that provides guidance and scientific advice on a low-request basis, serving as a clear incentive for academic centers, small and medium-sized pharmaceutical companies, and larger pharmaceutical organizations. The department holds portfolio meetings to identify upcoming innovative products, offering guidance to support their development. For promising innovations, efforts are focused on overcoming regulatory hurdles and ensuring compliance while also introducing stopping rules for products unlikely to succeed."*

"The pharma strategy process has been constructive, bringing fresh ideas and valuable insights. Even in legislation, introducing the Medizinforschungsgesetz (Medicine Research Act) is a positive step," sustains **Dr. Elmar Kroth**, Deputy General Manager, Pharma Deutschland, Germany, and states, *"the pharmaceutical industry has enormous potential to grow and flourish with the right framework. With its 84 million people, abundant physicians, pharmacists, and hospitals, Germany has the resources to excel."*

The Health Data Use Act: Pushing Digitalization in the Health Ecosystem

Beyond pricing and research, the strategy also looks to the future of healthcare through digitalization. The Health Data Use Act — known in German as the Gesundheitsdatennutzungsgesetz or GDNG — plays a key role in this transformation. The law aims to make health data more accessible and usable for both public and private research, while maintaining strong data protection standards. This includes reorganizing the national data infrastructure through a genome sequencing model project and creating a framework for a dedicated data protection authority to support cross-border research projects.

"BfArM has contributed to broader digital initiatives. Collaborating with health reform efforts, it has worked on classification systems and registries to support hospital reforms. A major milestone is the establishment of a terminology server, developed in partnership with Gematik, as a foundational element for Germany's electronic patient record. Another transformative project is the Health Data Lab. This initiative will integrate data from 74 million individuals covered by statutory health insurance, encompassing long-term and short-term data, hospital and ambulatory care records, prescription data, diagnoses, and disease progression. Over time, this will be supplemented with data from electronic health records, cancer registries, and digital health applications. The latter already has APIs for seamless integration, ensuring comprehensive and interoperable data." **Prof. Dr. Karl Broich**, President, BfArM

Dr. Frank Wartenberg, President Central Europe, IQVIA, observes: *"Germany has made significant strides in 2023 and 2024 in terms of healthcare digitization. After a lengthy period, e-pres-*

cription has been effectively introduced. According to our data, the adoption of e-prescriptions has been rapid and very robust. One of the accomplishments, in my opinion, is that three of the four prescriptions are now electronic. The creation of the electronic health record, which is anticipated to be implemented in 2025 onwards, is another accomplishment."

Growing Regional Resilience: Supply and Self-Sufficiency

Supply chain resilience is another major focus. Germany is offering investment incentives for pharmaceutical production facilities and grants to support long-term supply security.

"To build real resilience, we need production, or at least production capacity here in Europe", knows **Rabea Knorr,** Head of Department Health Industry, BDI, Germany: *"A big focus for us is improving early warning systems and driving the digitalization of supply chains to identify risks and shortages faster. At BDI, we are part of a government-funded consortium working closely with industry partners to explore how we can digitize supply chains from the ground up. Once you have that digital infrastructure, it's easier to track shortages early, take preventive action, and even advance* other goals like CO_2 tracking."

Leading one of Europe's largest CDMOs, **Jan Kengelbach**, CEO of Aenova Group, states: "*COVID-19 reminded everyone just how critical our industry is — and yet, Europe still faces persistent drug shortages, especially in generics. These aren't just due to supply chain issues in India or China; the bigger problem is that many products, especially older generics like antibiotics, have become commercially unsustainable. The key going forward is for policymakers and investors to recognize that pharmaceutical manufacturing is not just a cost but a strategic investment in Europe's health security.*"

Responding to the need beyond its own borders, Germany is actively contributing to the development of a new EU Critical Medicines Act, which sets out to ensure that essential drugs remain available and that Europe is less dependent on external markets.

Looking back at the reforms Germany initiated during the past year, it will now lie in the hands of the new elected chancellor and his coalition to further push a broader shift in Germany's approach to health policy. Rather than focusing solely on controlling costs, the government is now taking a more balanced view, one that seeks to support innovation, strengthen the country's scientific ecosystem, and prepare the system for future challenges. The industry is still skeptical, but with a record number of new medicines launched in 2024, Germany is showing early signs that its strategy might be ambitious but is also effective.

Germany's Healthcare Industry Key Facts

495 bn	+4.5 %	159.4 bn	162.7 bn
Healthcare Expenditure 2023 (in EUR)	Annual Market Growth (CAGR 2019-2023	Healthcare Exports (in EUR)	Healthcare Imports (in EUR)

Source: health-made-in-germany.com

The Hospital Reform: A Decisive Shift in Healthcare Delivery and Financing

In 2025, Germany's ambitious hospital reform is officially entering into force, marking a major shift in how care is delivered, financed, and structured across the country. While the reform aims to modernize the system and improve efficiency, its rollout comes with caution.

Marc Schreiner, CEO of the Berlin Hospital Federation and Chair of the Committee for EU and International Affairs at the German Hospital Federation, welcomed the intent to improve the system but warned about the starting point: "*This reform needs significant improvements. Beginning such a long-term reform, expected to last at least 10–15 years, with flawed legislation is concerning. Though slow to act, the federal health minister has a legal basis to issue three key regulations, which must be jointly decided with the federal states. These regulations include expanding the transformation fund, defining service groups for hospital planning, and setting minimum operation thresholds for hospitals*," he said.

A key component of the reform is a fundamental change to hospital financing. The reform reduces reliance on the Fallpauschale or Diagnosis-Related Group (DRG) system from 100% of hospital funding to 40%. The remaining 60% will now go toward supporting essential services such as staff, emergency rooms, and medical infrastructure. The goal is to ease the financial pressure on hospitals to focus on high-volume procedures and instead fund what is truly needed. *"Hospitals support restructuring and streamlining,"* says Schreiner; *"However, the funding issue needs to be well thought out to drive well-managed transformation.*

In addition, the reform promotes greater hospital specialization and the expansion of outpatient care, particularly in rural regions. Smaller facilities will be encouraged to focus on specific procedures, while rural clinics will be able to offer more specialist outpatient services, potentially relieving strain on central hospitals and improving local access.

Financial reform, however, is only one part of the challenge. The German healthcare system is already feeling the impact of a widespread workforce shortage. In Berlin, only 85% of hospital beds are currently usable due to a lack of personnel, a situation expected to worsen. *"A recent study found that Berlin will need an additional 10,000 full-time nurses by 2030*," **Schreiner** said, and pointed out that what is even more worrying is that the shortage extends beyond nursing. Many primary care positions remain unfilled, despite Berlin's status as an attractive and growing city. *"This issue will require a broader restructuring of the healthcare system, likely well beyond 2025 or 2030. As a nation, we must rethink our reliance on highly specialized care in primary and hospital care settings. We need to take on a more integrated approach that could redistribute responsibilities, especially as younger doctors increasingly prefer salaried, part-time roles without the financial risks of running private practices."*

Despite the controversy, the reform represents a major structural pivot for the German healthcare system. As implementation continues, its success will depend on how effectively stakeholders can navigate complexity, maintain access, and ensure that both financing and planning remain aligned with the core mission of patient-centered care.

Mikko Vasama, Managing Director, Philips Health Systems DACH, Germany, is optimistic and highlights the importance of a collaborative approach within the whole health ecosystem: "*We are here to help hospitals through our innovation, enabling agility and keeping a patient-first mindset. Beyond that, we also facilitate knowledge sharing, not only within Germany but across other markets. Coming from the Nordics, I often receive questions about how similar reforms were implemented in Denmark or Sweden. These discussions help hospitals navigate uncertainties by learning from international experiences. Ultimately, navigating these changes requires strong partnerships. Working closely with hospitals on the principles of collaboration allows us to adapt to the evolving landscape and develop solutions that provide the necessary flexibility on both sides".* For companies like Hologic, with a strong diagnostic portfolio, the evolving landscape of the hospital reform is both a challenge and an opportunity, particularly for specialties such as breast health, where timely coordination across care levels is essential. *"Germany's organized screening programs and designated breast centers play a key role,"* **Wouter Peperstraete,** General Manager DACH, shared, *"but questions remain about how these centers will link to local hospitals for chemotherapy and follow-up care to provide fast and accurate patient treatment."* Drawing on successful examples from other countries, Hologic sees potential in more centralized breast centers connected to regional hospitals, ensuring care continuity and local accessibility, a model that could inform Germany's next steps. Meanwhile, **Peperstraete** also highlighted concerns around the implementation speed and impact of reimbursement models, especially hybrid DRGs, which group inpatient and outpatient procedures under a single averaged reimbursement rate. While these mechanisms aim to support efficiency and flexibility, they can pose a dilemma. *"This system creates a single reimbursement rate by averaging costs, even though specialized interventions like ours are more expensive. This could result in a choice where the best patient treatment is not always favored compared to the financial profits."* Despite these concerns, Hologic sees new pathways opening, including the ability to enter procedure areas such as polyp or myoma removal, where their high-tech solutions can now be reconsidered under hybrid reimbursement terms.

Prof. Dr. Karl Broich

BfArM,
President

EF: How has the regulatory landscape evolved over the past two years, and how have your priorities changed?

KB: In comparison, there is a stronger focus on digitalization. We are witnessing a surge in digital health applications while discussions about digital care applications are gaining traction publicly. However, challenges persist, such as drug and medicinal product shortages.

A key concern remains accelerating the pace of innovation. How can we expedite clinical trials in Germany? Additionally, how can we effectively implement the requirements outlined in the Medical Research Act? This legislation has prompted closer collaboration with the Paul-Ehrlich-Institut. Significant changes are underway, and with the upcoming launch of the Digital Health Data Lab this year, we anticipate a transformative impact on patient care in Germany.

EF: Could you elaborate on how you foster and promote innovation?

KB: In response to the requirements set forth by the Medical Research Act, BfArM has established a dedicated Department for Innovation Management. This department houses an Innovation Office that provides guidance and scientific advice on a low-request basis, serving as a clear incentive for academic centers, small and medium-sized pharmaceutical companies, and larger pharmaceutical organizations. The department holds portfolio meetings to identify upcoming innovative products, offering guidance to support their development. For promising innovations, efforts are focused on overcoming regulatory hurdles and ensuring compliance while also introducing stopping rules for products unlikely to succeed.

Looking ahead, this department will play a central role in managing the Special Ethics Committee, which is another key component of the Medical Research Act. This committee is designed to oversee and enhance specialized, innovative clinical trials, such as those conducted during pandemics, platform trials, first-in-human trials, or advanced therapy medicinal products (ATMPs).

Germany has historically been slower in initiating clinical trial recruitment than other countries. To address this, the BfArM has, amongst others, strengthened its Department for Clinical Trials and Governance, fostering closer collaboration with institutions like the Paul-Ehrlich Institute. Steps include harmonizing websites, centralizing requests from industry and stakeholders, and especially creating a single entry point on the BfArM website for applications, including scientific advice. This streamlined process allows for faster processing on all sides, faster decision-making, and better coordination among departments.

Additionally, BfArM has established a Division for Regulatory IT and a Coordination Office. This division is focused on leveraging digital tools and AI to enhance marketing authorizations, clinical trials, and scientific advice. Efforts include developing common IT solutions in collaboration with the Paul-Ehrlich-Institut and ensuring alignment with the European Medicines Agency's systems.

To reduce bureaucracy, BfArM has prioritized essential regulatory requests and moved away from redundant or outdated requirements. Emphasis is placed on rethinking digital transformation from the ground up, avoiding merely replicating analog processes in digital formats. **EF: Could you elaborate on the role BfArM plays in shaping Germany's e-health infrastructure?**

> "Germany has been a pioneer in integrating digital healthcare applications into its system, starting with the fast-track procedure for approval, followed by the ability to prescribe and reimburse these applications. Currently, 58 digital health applications are listed on the BfArM website. Most of these focus on psychiatric indications, as cognitive behavioral therapy approaches are relatively straightforward to translate into digital formats."

BfArM remains committed to advancing digital health applications and ensuring they have a defined role in the healthcare system. However, digital care applications face greater hurdles. Many applicants report that the current financial model, is not viable. BfArM is actively engaging with policymakers and the ministry to address these barriers and create a more attractive system for future applications.

In parallel, BfArM has contributed to broader digital initiatives. Collaborating with health reform efforts, it has worked on classification systems and registries to support hospital reforms. A major milestone is the establishment of a terminology server, developed in partnership with Gematik, as a foundational element for Germany's electronic patient record. This record was recently launched as a pilot in three regions and represents a significant step forward in digital health infrastructure.

Another transformative project is the Health Data Lab. This initiative will integrate data from 74 million individuals covered by statutory health insurance, encompassing long-term and short-term data, hospital and ambulatory care records, prescription data, diagnoses, and disease progression. Over time, this will be supplemented with data from electronic health records, cancer registries, and digital health applications. The latter already have APIs for seamless integration, ensuring comprehensive and interoperable data.

This vast repository of health data holds immense potential for medical research and innovation, aligning with the vision of the European Health Data Space. Germany has actively participated in pilot phases to shape this initiative, ensuring its data are ready to be utilized within the European framework. The recent endorsement of this approach by the Council represents a significant step forward in leveraging health data for improved care and innovation across Europe.

EF: Reflecting on your time leading BfArM, what accomplishments are you most proud of as President? What are your aspirations for the future?

KB: I am truly excited to continue following the developments and strengthening our role as a trusted and open-minded partner in healthcare innovation. My focus has been on fostering European collaborations with organizations like EMA and the European Commission, co-chairing initiatives such as Darwin EU. Looking ahead, a key area of focus will be our new Network Data Steering Committee, where we will discuss the use of AI applications for regulatory purposes.

One of my priorities is exploring how we can leverage large language models in regulatory science to improve process management and introduce automation.

I am confident that in the next 5 to 10 years, our healthcare system will be entirely data-driven, which presents exciting opportunities. I am a neurologist and psychiatrist by training, and I am especially looking forward to the progress in treating Alzheimer's disease and other CNS indications like schizophrenia.

Dr. Elmar Kroth

Pharma Deutschland
Deputy General Manager

EF: Could you give us a brief overview of your top priorities, how you identify them, and how you plan to tackle them?

EK: Our focus is promoting self-care and empowering patients to take charge of their health. Self-care is vital to any modern healthcare system because it gives patients more control and autonomy over their well-being. To support this, we need a more flexible framework. In Germany, the rules for self-care, especially for products to switch from prescription-only to pharmacy-only, are very rigid and have remained unchanged for 45 years. Such products are essential for keeping the market dynamic, but the current system limits their potential. Modernizing this framework is a key priority for us.

With the transition from BAH to Pharma Deutschland, we're embracing a broader role to represent the entire pharmaceutical market in Germany. This includes everything from OTC products and homeopathies to highly innovative medicines like ATMPs. However, the AMNOG system for early benefit assessments, which determines innovation prices, needs improvement. To support new advancements and maintain Germany's competitive edge in Europe, Germany must adopt the AMNOG system. Rather than a complete overhaul, it's about gradually evolving the system to align with current and future needs.

The third priority concerns addressing shortages in the job and other European markets. We need solutions to avoid these shortages and secure robust supply chains. We have faced challenges like other European countries, which makes improving our pharmaceutical supply throughout Germany a priority. To tackle this, we're exploring flexible procurement strategies and market-based solutions. Market-based approaches are important because government intervention is not the answer. Instead, we propose promoting essential medicines within Europe, supported by incentives. Pricing shouldn't be the only factor; we must also consider production location as a second important criterion.

Our fourth priority is adapting the Urban Wastewater Treatment Directive (UWWTD), which will place a massive financial burden on the pharmaceutical industry. In Germany, the cost of upgrading wastewater facilities to reduce micro-pollution exceeds €2 billion annually, equivalent to the entire generic pharmaceutical market's value. This hits generic producers the hardest since older substances are often more eco-toxic than newer biotechnology products. If this directive is enforced in its current form, it could severely impact the generic market.

We need creative strategies for safer water that don't place such a heavy burden on just two industries: pharmaceuticals and cosmetics. Many sectors like the chemical, agriculture, traffic, and energy sectors also contribute to micro-pollution, but they are not held accountable. It makes the imbalance unfair and poses a risk that it could disrupt supply chains and markets. Therefore, addressing this unfairness and finding a balanced approach to avoid further shortages is crucial.

EF: How do you assess the impact of the national pharmaceutical strategy?

EK: The pharmaceutical industry is one of the most thriving sectors in Germany, especially compared to the challenges the automotive industry has faced in recent years. While the automotive sector excelled in traditional manufacturing, it has struggled to adapt to the shift toward e-mobility. Conversely, the pharmaceutical industry has been growing because of the strong ecosystem of global players, mid-sized companies, and innovative research-based organizations and the support they bring. Healthcare overall is Germany's largest industry, encompassing hospitals, physicians, pharmacists, nursing homes, and other service providers. It's a growing sector with increasing income and demand. However, like other industries, we face rising energy costs, price increases, and workforce shortages. We need more skilled specialists, including talent from outside the country, to address this.

We're pleased to be part of discussions with the government to address these issues. The pharma strategy process has been constructive, bringing fresh ideas and valuable insights. Even in legislation, introducing the Medizinforschungsgesetz (Medicine Research Act) is a positive step. While it's just the beginning, it lays the groundwork for further progress.

EF: Could you give us more details on how Pharma Deutschland promotes a real preventative approach?

EK: On the political side, we're advocating for improvements to the regulatory framework for product switches. The process is overly complex, time-consuming, and often unpredictable, making it challenging to achieve profitable outcomes. Streamlining this process is one of our key recommendations to policymakers. We're also strong supporters of local pharmacies and often run campaigns to highlight their role as trusted points of contact where patients can receive advice and access safe products.

EF: Are there any specific collaborations from the association or the members with success stories of how Germany thrives in this sector?

EK: One example we're proud of is the green prescription initiative. It addresses the gap where physicians recommend OTC products but cannot prescribe them formally. Patients often forget these recommendations, so the green prescription bridges the gap. It looks like a standard prescription, like a red prescription for prescribed medicines, but is used for OTC products. About 90% of patients with a green prescription present it at the pharmacy and purchase the recommended product alongside their red prescription. This is a great example of the collaboration between industry, pharmacies, and physicians. It highlights how partnerships among all three stakeholders can create meaningful solutions that benefit everyone.

EF: Is there any final message, recommendation, or reflection on your work you would like to share with our readers?

> **"The most important thing is reminding politicians that the pharmaceutical industry is a key part of Germany's economy and innovation. With its 84 million people, abundant physicians, pharmacists, and hospitals, Germany has the resources to excel."**

However, clinical trials and other areas have been declining in recent years. To reverse this, politicians must prioritize the health sector, not just financially but holistically.

Currently, 70–80% of active pharmaceutical ingredients (APIs) are produced in India and China, making us heavily dependent on Asia. In order to achieve this, our primary goal is to maintain existing production facilities in Germany. Therefore, the financial framework and, ultimately, drug prices must be improved. If this is successful, options for relocating production facilities to Germany and Europe can be considered. Lastly, both innovative and generic industries are essential. It's not about choosing one over the other; they complement each other. We need policies that enable both to thrive because both are critical to the pharmaceutical ecosystem.

Marc Schreiner

Berlin Hospital Federation & German Hospital Federation Chief Executive Officer, Berlin Hospital Federation and Chair of the Committee, EU/International Affairs, German Hospital Federation

EF: Could you give us your reaction to the hospital reform and how will it affect the health ecosystem?

MS: The Council of Federal States (Bundesrat) approved the reform, which will now be published by the federal president, taking effect in 2025. It is widely acknowledged that this reform is poorly designed and needs significant improvements. Beginning such a long-term reform expected to last at least 10–15 years with flawed legislation is concerning. Politicians should have recognized their responsibility earlier, but they didn't. Now, ministerial decisions are needed to address gaps. Though slow to act, the federal health minister has a legal basis to issue three key regulations, which must be jointly decided with the federal states. These regulations include expanding the transformation fund, defining service groups for hospital planning, and setting minimum operation thresholds for hospitals.

The health minister announced that the first regulation regarding the €50 billion transformation fund was ready for co-decision. Starting in 2026, the fund aims to invest €5 billion a year, with the costs split equally between the federal government and the states; however, disagreements over where the money should come from created tension within the coalition. The finance minister refused to use federal funds, so the health minister decided to pull money from health insurance reserves instead. This decision has sparked controversy, as it uses money meant for insured individuals, and this will likely end up in court.

The reform introduces new hospital planning methods using service groups. North Rhine-Westphalia has already piloted this model, using 60 service groups for its hospital plans. The latest reform mandates adding five more service groups to the existing 60. This mandate creates uncertainty about how the new service groups can fit into the existing ones.

Despite its shortcomings, the reform offers a starting point for change. Hospitals support restructuring and streamlining. However, their biggest drive and priority is that the reform needs to be more organized and well-thought-out. The funding issue needs to be well thought out to drive well-managed transformation. Instead, the current structure could lead hospitals toward bankruptcy, leading to unplanned closures. The process needs to be guided by clear and sustainable strategies to improve truly healthcare.

EF: How have you identified the lack of healthcare personnel going into the next fifteen years, and what are you doing about it as the federation to address it?

MS: We already feel the strain of understaffing in Berlin's healthcare system. For instance, only 85% of hospital beds are usable due to a shortage of health workers, a problem expected to worsen. A recent study commissioned for 2030 found that Berlin will require an additional 10,000 full-time nurses to support its expanding and aging population. In response, we launched a campaign in 2020, complete with a dedicated website to address this challenge. We're exploring all options to boost nursing capacity, from improving education and working conditions to integrating foreign nurses and creating more recognition for the profession. We're also encouraging former nurses to return to work and even helping healthcare workers find affordable housing, which is becoming increasingly scarce in Berlin.

> "As a nation, we must rethink our reliance on highly specialized care in primary and hospital care settings. We need to take on a more integrated approach that could redistribute responsibilities."

Especially as younger doctors increasingly prefer salaried, part-time roles without the financial risks of running private practices.

Another challenge lies in educating the public. People need better health literacy—not just to maintain their health and avoid risks but also to navigate the healthcare system effectively. Too many patients visit expensive hospital emergency facilities for issues that could have been managed more affordably in primary care. We can promote telemedicine and primary care hotlines for simpler needs instead of patients heading straight to specialized care. It's not just about reforming institutions but also about empowering people to use the system more efficiently. This will save money and ensure resources are available when truly needed.

EF: How are you investing in new devices and processes to enhance the digitalization of hospitals, and how can you ensure this technological investment is sustainable?

MS: Hospitals showed great effort and adapted to new systems with forms and decision-making processes when applying for a 4,3 billion Euro "future fund." This fund had been set up in order to lift Germany's hospitals to the next level of digitalization maturity. But we faced challenges. Bureaucracy worked as expected, but delays and quality issues emerged once 1,700 eligible hospitals began ordering the same products and services from a limited number of providers. As a result, hospitals didn't receive what they initially expected. To deal with this, we've extended the deadline by a year, including holding off on penalties for hospitals that couldn't meet the requirements on time. Despite these challenges, the investment did lead to significant progress. We've seen a real digital boost in hospitals backed by research, but making this progress sustainable is tricky.

Keeping hospitals at this higher digital level is a costly undertaking. There are constant costs for renewing licenses, updating hardware and software, and reinvesting in systems. None of this is currently built into the way hospital funding works. The federal states responsible for hospital investment funding struggle to cover basics like buildings and equipment. Adding digital infrastructure and personnel to their plate is a whole new challenge.

Then, there's the issue of finding the right people to handle these increasingly complex digital systems. Hospital IT is unlike any other IT; it has to integrate everything from medical devices to doctors and nurses, and it's incredibly specialized. This requires highly specialized IT staff, but hospitals face tough competition from other industries that offer better pay. We've started working with universities to develop specialized study programs to tackle this. The idea is to train the IT professionals we need to manage and grow these systems. If we want this investment to last, we must keep building the right infrastructure and bringing in the right people. It will take a lot of effort, but it's the only way to make this work long-term. We have to start immediately with the training.

EF: From many of your members from the federation, are there any key success stories you would like to share?

MS: Regarding digitalization, we're incredibly proud of our progress with some of our largest public hospitals. Charité University Hospital Berlin and Vivantes, Germany's largest community hospital, teamed up to develop a platform for electronic patient records. With this system, doctors at one hospital can securely access a patient's medical history from another—provided the patient consents. It makes sharing important information from past hospital visits across different facilities much easier. Beyond these two major hospitals, we worked closely with the Berlin Hospital Federation to bring many other hospital operators on board. Today, the platform covers nearly 85% of all hospital beds in the city. It's a great example of how sharing knowledge and resources can improve patient care.

Chapter 2

Industry Opportunities

"Investing in Germany would be prudent given our capacity for both organic and acquisition growth, particularly in light of our strategic decisions and expansion into the larger healthcare system. The market is becoming more and more attractive, the population is increasing, and the environment is favorable. It appeals to the life sciences sector. The healthcare system is at a turning point in terms of digitization and needs to increase productivity. Thus, the opportunities are numerous." **Dr. Frank Wartenberg**, *President of Central Europe, IQVIA*

The Land of Ideas: Bringing Innovation Back Home

Amid growing global uncertainty, businesses are looking for stable, innovation-friendly environments for research, development, and production. Germany stands out with its strong industrial base, skilled workforce, and increasing openness to digital health solutions. As the population continues to age and healthcare needs evolve, new opportunities are emerging, not just in pharmaceuticals, but across the wider healthcare system. The shift toward digital services, now increasingly recognized and reimbursed by insurers, is opening new market segments and driving innovation across the country.

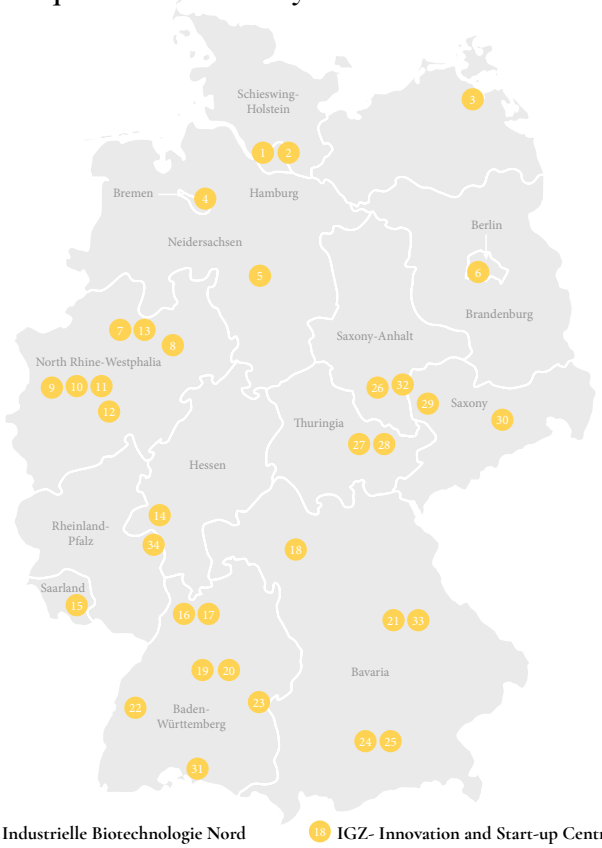
"Germany is leveraging its well-established ecosystem to drive collaboration and innovation; second, it is creating conditions for new players to enter and thrive, further strengthening the resilience and future competitiveness of the healthcare and pharmaceutical sectors," knows **Achim Hartig**, Managing Director of GTAI and Chair at the OECD IPA Network, aware of how Germany has reinforced its role as a leading destination for healthcare and pharmaceutical investment, and elaborates: *"We are focused on building long-term resilience in both the pharmaceutical and healthcare sectors. Germany can support complex, high-level innovation through local networks and partnerships. At the same time, the country is making it easier for venture capital to enter the market, opening up new pathways for startups to grow. Supporting them helps inject fresh innovation into existing value chains and gives rise to future market leaders."*

Organizations like BioM Biotech Cluster Development GmbH are actively focusing on driving Germany's resilience and leadership in innovation from within: *"Our goal has always been to drive continuous innovation and successfully translate research into sustainable products, creating a long-term, self-sustaining market. Rather than relying solely on external innovation or waiting for others to acquire our advancements, we aim to build upon our strong foundation of excellent science and research. It is essential that we take discoveries from the bench to the market, ensuring their full potential is realized,"* explains the Managing Director, **Prof. Dr. Ralf Huss**.

Meanwhile, Germany's forward-looking framework is attractive for external players as well. In the past years, global companies have announced major expansions, with investments ranging from hundreds of millions to over two billion euros. These commitments reflect not only confidence in Germany's pharmaceutical sector but also the broader strength of its healthcare landscape.

"Germany is the beating heart of Europe, and we are here to help hospitals provide better care for more people through meaningful innovation. It has excellent research facilities, world-class hospitals, and a reputation for delivering precision innovation. Therefore, I can not emphasize the size and significance of the German healthcare market." **Mikko Vasama**, *Managing Director, Philips Health Systems DACH, Germany*

Biotechnology Clusters ("BioRegions") and their Headquarters in Germany



1 Industrielle Biotechnologie Nord
2 Life Science Nord
3 BioCon Valley
4 BioNord
5 BioRegioN
6 HealthCapital Cluster Gesundheitswirtschaft in Berlin
7 Gesellschaft für Bioanalytik Münster
8 BioIndustry
9 BIO.NRW
10 BioRiver - Life Science in the Rheinland
11 BioCologne
12 MedLife e.V
13 bioanalytik-muenster
14 Technologieland Hessen
15 cc-NanoBioNet e.V.
16 BioRN - Life Science Cluster Rhine-Main-Neckar
17 Technologiepark Heidelberg
18 IGZ- Innovation and Start-up Centre Wurzburg
19 BIOPRO
20 BioRegio Stern Management GmbH
21 BioPark Regensburg
22 BioRegio Freiburg - BioValley
23 BioPharma Cluster South Germany
24 BioM - Munich Biotech Cluster
25 Cluster Offensive Bayern
26 BMD Life Sciences Agency
27 InfectoGnostics Forschungscampus Jena
28 Medways
29 Bio City Leipzig
30 biosaxony
31 BioLAGO - the Health Network
32 Technologiepark Weinberg Campus
33 BioRegio Regensburg
34 Cluster für Individualisierte ImmunIntervention e.V. (Ci3)

Source: GTAI

Investments in healthcare are

As a key industry for Germany, we provide a valuable contribution for patients, science, and the economy.

investments in society.

A Gain at All Levels

Medical innovations are more than just incremental progress – they are a long-term investment in health, science, and the economy. As a leading research company, we drive new therapies that sustainably improve patient care. However, research requires predictability and reliability. Therefore, we advocate for stable framework conditions. For medical innovations that have a long-lasting impact. For a healthcare system that benefits everyone.

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A Safe Bet: Growth Made in Germany

Germany continues to attract long-term investments from global pharmaceutical and life sciences companies, thanks to its strategic position, strong healthcare infrastructure, and commitment to innovation.

Many players have deepened their local roots, expanding both their operational and research capacities. One notable example is CSL Behring, which has grown from a local success story into a global force while maintaining its strong connection to Germany. *"CSL has invested more than €600 million in the Marburg site in recent years, including a state-of-the-art base fractionation and one of its largest R&D centers in the world, located in the heart of Germany. Additionally, we operate 17 plasma collection centers across the country, ensuring we maintain a strong and independent supply chain, reducing reliance on plasma collected in the U.S., especially given global uncertainties like elections and policy changes. Germany is one of our most important markets, not just for business growth but also for research and manufacturing. The country has a strong ecosystem for the plasma industry, and we want to ensure it remains attractive in the future."* **Christian Wieszner,** Managing Director and Vice President DACH Cluster.

Germany's strength is not only in its domestic capabilities but also in its broader role within Europe's innovation ecosystem. **Achim Harting** from GTAI emphasizes this broader context, stating, *"Germany is deeply embedded in a network of international supply chains and R&D collaborations across Europe. Rather than viewing Germany in isolation, it makes more sense to see it as a central hub within a wider European framework."*

Chances for Newcomers

This centrality has attracted new entrants from across the continent, including, for example, major players from Italy. IBSA has recently made Germany a cornerstone of its European strategy. As Germany's General Manager, **Marion Bock** puts it, *"To be a truly European and global company, having a direct presence in Germany is non-negotiable. If you want to be a major player in Europe, you must invest in Germany. While the return on investment may not match that of rapidly growing markets, investing in Germany builds a strong reputation and establishes a solid foundation for long-term business success. We offer a complete portfolio in reproductive medicine, covering every phase of treatment."*

Angelini Pharma shares this view and has made Germany a pillar of its long-term vision. **Johannes Inama**, General Manager for the company in Germany, explains, *"A European growth strategy would be incomplete without Germany, given its position as the largest economy and country in Europe. This recognition led to the establishment of the German affiliate in 2020. Germany is destined to become a core pillar of Angelini Pharma's international success. Our approach focuses on maintaining and growing the strong consumer health pillar, primarily around the key brands. At the same time, we are committed to accelerating the development and growth of our epilepsy therapy, which is still in the early stages of its lifecycle. Together, these priorities ensure a balanced and sustainable strategy for the success of our operations in Germany."*

Longstanding Commitment

Legacy players already well established in the country are also ramping up their investments. Roche, looks back on a 127 year history in Germany and yet, continues to expand significantly German CEO, **Dr. Daniel Steiners** reflects on this commitment: *"Roche's investment volume in expanding our production, research, and administrative facilities in Germany has totaled over 3 billion euros in the past five years, and the future will largely depend on continued support from the German government to improve the policy frameworks. With ongoing investment, Roche is poised to further expand its footprint in Germany, contributing to the country's growth as a hub for the pharmaceutical industry."*

Nonetheless, Germany's appeal also reaches beyond the borders of Europe. AstraZeneca, originally from Oxford but now a global leader in R&D, continues to prioritize the German market. As German Country President **Alexandra Bishop** explains, *"What Germany brings to the table is significant: a highly skilled workforce, as well as some of the top healthcare institutions, academic hospitals, and researchers, offering a very high level of expertise. We are currently one of the leading companies in clinical research in Germany. We want to do even more. There is a clear opportunity to not just attract investments in this area but to ensure Germany stays at the forefront of innovation and research."*

This deep commitment is shared by Teva Pharmaceuticals which transformed its footprint in Europe through a strategic acquisition in Germany. **Andreas Burkhardt,** SVP General Manager, Teva Pharmaceuticals, Germany & Chair at ProGenerika, Germany, recounts: *"Germany's importance grew significantly with Teva's acquisition of Ratiopharm. The acquisition elevated Teva's position in Germany from 15th or 20th place to 1st or 2nd, underscoring the strategic value of the German market. Additionally, Teva has established complex production capabilities in Germany, particularly in Ulm. Germany has one of the highest generic conversion rates, with 80% of medications being generics. However, the country increasingly depends on Indian and Chinese suppliers. While there is nothing inherently wrong with these suppliers, an overreliance creates vulnerabilities. Our goal is to secure a stable supply chain for patients while supporting the broader industry. Ensuring patients have reliable access to medication is a duty we take very seriously."*

From global manufacturers to fast-growing innovators, the message is clear: Germany offers a reliable foundation for companies committed to long-term investment, research excellence, and collaborative innovation. The momentum in the market reflects not only its past achievements but also a strong belief in the future of German healthcare.

"Despite all of our issues as a country with a highly complex administration, we still have a strong and unique foundation. Germany is one of the biggest pharmaceutical markets in the world that is still well-funded, and medical innovations are rapidly available for the masses of patients compared to other states within the EU and beyond."
Dr. Frank Wartenberg, *President, Central Europe, IQVIA*

THE MEDICAL BIOTECHNOLOGY INDUSTRY IN NUMBERS

35%
market share of total pharmaceutical market

10.7%
CAGR for the period 2024 to 2032

2.346
biotechnology patent applications

776
dedicated companies in the biotechnology sector

Source: health-made-in-germany.com

Rabea Knorr

BDI

Head Of Department Health Industry, Germany

EF: How are the current developments in Germany shaping BDI's priorities? Where do you see both challenges and opportunities, particularly for the healthcare sector?

RK: My team focuses specifically on the healthcare industry. We look at innovation strategies, production plans, and key challenges — especially digitalization, an area where Germany, including its healthcare system, still lags behind. The government's vision for the future of healthcare and how our industry can contribute to it, are therefore central themes for us. But healthcare is just one part of a broader conversation. Across all sectors, one of the biggest priorities is improving Germany's competitiveness. In today's geopolitical environment, both Germany and Europe must strengthen their position by using the tools available: cutting bureaucracy, reducing regulatory hurdles to foster innovation, lowering taxes, and tackling high energy costs. These fundamentals will be critical to maintaining our industrial strength moving forward.

EF: How does BDI actively influence healthcare policy? What is your strategy for advocating industrial interests within this new framework, particularly for the healthcare sector?

RK: At BDI, our core strategy is to position the health industry as an integral part of economic and industrial policy. Our role is to connect the dots across pharma, medical devices, biotech, health IT, and the broader health ecosystem — and bring that perspective to economic policymakers, not just those focused on healthcare. Our message is clear: the health industry is a key pillar of stability and growth. It is a major driver of jobs, innovation, and resilience. In today's world, national security is no longer just about defense or energy. We need to have a strong, innovative health industry capable of responding to future crises.

> "Healthcare is not only about treating patients, it is about building the foundation for a stable and sovereign economy."

EF: What do you see as the critical steps Germany needs to take to become more self-sufficient?

RK: To build real resilience, we need production — or at least production capacity — here in Europe. That is the starting point. However, it is not just about manufacturing itself; supply chain resilience is equally important. And that means creating the right incentives to make both happen. A big focus for us is improving early warning systems and driving the digitalization of supply chains to identify risks and shortages faster. At BDI, we are part of a government-funded consortium working closely with industry partners to explore how we can digitize supply chains from the ground up. Once you have that digital infrastructure, it's easier to track shortages early, take preventive action, and even advance other goals like CO_2 tracking. We are also looking at best practices from other industries. For instance, the automotive sector built a data space years ago to monitor container shipments. Inspired by that, we are now adapting the model for healthcare through our "HealthTrack-X" project — creating a dedicated data space to track and secure medical supply chains.

EF: What will it take for Germany to reclaim its reputation as a nation of thinkers and innovators? How do associations like BDI help encourage that shift back to innovation?

RK: At BDI, innovation is a strong point across many sectors, including health. While AI breakthroughs — especially large language models — are often linked to the US and China, Germany remains competitive when it comes to applying AI in production and manufacturing. This leadership is bolstered by our highly qualified workforce and the collaborative environment fostered by institutions like university hospitals, which are significant factors attracting health industry investments to Germany.

Nonetheless, bureaucracy, taxation, and energy costs can impede innovation. We need structural reforms to free up companies, especially smaller ones, so they can focus more on innovation rather than red tape. Another hurdle is funding for startups and scale-ups. Germany needs more venture capital to help innovative projects grow. The Health Data Utilization Act (GDNG), enacted in early 2024, aims to improve access to health data for research purposes. This law enables the industry to use health data to boost research and innovation. However, the data still needs to be better connected and more reliable, meaning structured and of high quality. The Act is a solid first step, but more work is required to build a strong, integrated health data system.

EF: If you look back at your career trajectory, what is one of your proudest moments? And what is a personal achievement you still look forward to?

RK: One of our biggest successes over the past two years has been laying the groundwork for a health industry data space called "sphin-X". We've worked hard to shift mindsets in the sector, helping companies understand that true digital transformation cannot happen in isolation.

Sphin-X is bringing together over 20 companies committed to accelerating this collaborative approach. Germany needs a unified health data ecosystem to boost research and innovation, and combining projects like sphin-X with other lighthouse projects would make it easier for the industry to access and use data. This, in turn, would strengthen Germany's position in health R&D, since access to health data is one of the key factors when deciding on where to locate R&D. High-quality data is essential for progress, and using standards like FHIR ensures smooth integration across platforms.

Looking back at the digital legislation introduced two years ago, there was considerable debate among companies about how positively we should respond. Giving industry access to health data was a big step, but putting it into practice remains challenging. Connecting the data and ensuring its quality will take time. Still, it's a crucial step in the right direction and could help draw more AI research and investment to Germany.

Achim Hartig

GTAI & OECD IPA Network
Managing Director, GTAI & Chair, OECD IPA Network, Germany

EF: What are your current priorities in 2025?

AH: We are managing substantial FDI from a variety of industries, looking at the healthcare and pharmaceutical sectors. Significant investments in Germany have continued. Major investments include a €2.3 billion investment by Lilly and €1 billion by Daiichi Sankyo, along with additional rounds of €600 million by Roche, €150 million by AbbVie, and €1.3 billion by Sanofi.

Although these figures pertain specifically to pharmaceuticals, the overall healthcare sector is even larger, and digital healthcare services are emerging as a rapidly expanding field. The stable growth experienced over the past two years is driven in part by increasing global uncertainty. This uncertainty prompts companies to diversify their supply chains and seek secure regions for production and research and development, with Europe—and Germany, in particular—standing out as a hub of excellence with robust industry ecosystems.

Moreover, shifting demographics in Europe, offer opportunities for healthcare and pharmaceutical service providers. As populations age and healthcare needs evolve, these sectors are poised to grow. Changes in the regulatory environment have also played a role; regulators have slowly embraced digital services, opening up new segments where such services can be prescribed by doctors and reimbursed by health insurers. These factors collectively have created new markets and spurred innovation in Germany.

EF: How can Germany capitalize on geopolitical shifts as EU policymakers push for more strategic autonomy?

AH: The pandemic clearly highlighted the risk of relying on just a handful of supply chains or vendors. Germany, in response, has been actively working to strengthen its national and broader European ecosystems. It is difficult to draw a sharp line between the two since Germany is deeply embedded in a network of international supply chains and R&D collaborations across Europe. Rather than viewing Germany in isolation, it makes more sense to see it as a central hub within a wider European framework.

We recognized the urgent need for greater autonomy, and we began to build that capacity in real time. Take the example of BioNTech and Pfizer. Beyond developing a successful vaccine, BioNTech established over 1,200 contracts with local partners within Germany to support its production and delivery. That level of coordination reflects the strength and potential of Germany's innovation ecosystem in pharmaceutical manufacturing. We are really focused on building long-term resilience in both the pharmaceutical and healthcare sectors.

At the same time, Germany is making it easier for venture capital to enter the market, opening up new pathways for startups to grow. Many of these startups are not yet profitable but are developing cutting-edge solutions that could reshape the industry. Supporting them helps inject fresh innovation into existing value chains and gives rise to future market leaders.

There are two key dimensions here: first, Germany is leveraging its well-established ecosystem to drive collaboration and innovation; second, it is creating conditions for new players to enter and thrive, further strengthening the resilience and future competitiveness of the healthcare and pharmaceutical sectors.

EF: How important is a strong digital health infrastructure for attracting investment?

AH: This is a medium-term goal for Germany. While we may not be the fastest in adopting digital technologies, we are now seeing concrete steps being taken in the right direction. One key development is introducing the electronic patient record, or *ePA*, which is an important milestone.

What is promising is how Germany is beginning to make health data accessible for research and development. The regulatory framework is evolving to allow data from electronic patient records to be combined with information from health insurance providers, enabling its use in research while still upholding Germany's strong data protection standards. That balance of maintaining privacy while unlocking value for research is a breakthrough.

This shift opens up new market opportunities in several ways. First, it allows digital services to become more efficient and targeted, which, in turn, makes them more attractive and scalable. Second, digital healthcare solutions improve access to care for individuals who may struggle to reach a doctor—whether due to geography, mobility, or other constraints—and digital tools provide an alternative that brings more people into the healthcare system. With a population of over 83 million, the potential to expand access and grow the market is significant.

EF: How do you assess the current trends in AI?

AH: Ultimately, it comes down to data analytics and solution generation. We are seeing that the development of AI models is accelerating at a remarkable pace. Whether you look at Perplexity, OpenAI, or others, they are all pushing to reduce error rates and improve the accuracy of their outputs.

This is especially relevant in highly complex fields, such as genome analysis, genetic data interpretation, personalized medicine, and molecule design in the pharmaceutical industry. AI is becoming a unifying force across domains—from medical imaging and drug discovery to surgical robotics and assistive technologies like exoskeletons. The scope of its applications seems limitless.

EF: When you work on building partnerships, how do you communicate the continued attractiveness of investing in Germany?

AH: Right now, there is a lot of commentary, particularly from domestic companies, about challenges such as rising energy costs and regulatory complexity. However, it is important to recognize that foreign companies often view Germany through a different lens. When they assess global investment opportunities, they compare countries based on factors like political stability, legal reliability, and economic strength. These fundamentals often narrow their choices significantly.

For companies looking specifically at Europe, the list of viable options becomes even more focused. And when you consider sectors like healthcare and pharmaceuticals, only a few countries emerge as truly attractive. Germany consistently stands out due to its strong market size, regulatory predictability, and industrial infrastructure.

We also highlight Germany's proven track record of building up industries and its deep expertise in the life sciences sector.

> **"When we speak to companies or potential partners, we frame the conversation around this layered view: from macroeconomic and geopolitical strengths to sector-specific expertise and ecosystem advantages, Germany offers a compelling case for continued investment and innovation."**

Dr. Frank Wartenberg

IQVIA
President Central Europe

EF: How have your priorities changed over the past two years, and what market trends do you anticipate in 2025?

FW: The main goal of the past two years has been to keep moving forward with our mission to assist people in living longer, healthier lives. One of the components of our overall objective to reach out to broader healthcare is the transformation of the healthcare system. This implies that we will be more involved in the area of sickness funds and regulatory bodies, especially in Germany. For instance, we assist the BfArM by taking steps to monitor and stop shortages of medicines. We are the elected partner to handle the medicine shortages in Germany, and we have achieved traction of being more relevant to the healthcare system overall, even at an EMA level.

Germany has made significant strides in 2023 and 2024 in terms of healthcare digitization. After a lengthy period, e-prescription has been effectively introduced. According to our data, the adoption of e-prescriptions has been rapid and very robust. One of the accomplishments is that three of the four prescriptions are now electronic. The creation of the electronic health record, which is anticipated to be implemented in 2025 onwards, is another accomplishment.

As IQVIA, we take great pride in the fact that, in conjunction with the association of research institutes, we were able to support the legislation surrounding clinical research with insights from our day-to-day work. In this context, I can also say that, as an organization, we have been able to enroll the first patient in studies more quickly than ever before, which is significant. Getting your therapies to patients as soon as feasible is crucial if you have effective treatments.

EF: What is Germany's strategic importance to IQVIA?

FW: First off, in terms of revenue, Germany is currently the second-largest prospect worldwide. As a result, investing in Germany would be prudent given our capacity for both organic and acquisition growth, particularly in light of our strategic decisions and expansion into the larger healthcare system. Despite all of our issues as a country with a highly complex administration, I think we still have a strong and unique foundation here since Germany is one of the biggest pharmaceutical markets in the world that is still well-funded, and medical innovations are rapidly available for the masses of patients compared to other states within the EU and beyond.

Overall, the quality of healthcare in Germany does have the potential to reduce bureaucracy, and it has this massive openness to innovation. The market is becoming more and more attractive, the population is increasing, and the environment is favorable.

> "The healthcare system is at a turning point in terms of digitization and needs to increase productivity. Thus, the opportunities are numerous. IQVIA must keep making investments."

An area that IQVIA is focused on is selective contracting, which helps directly improve care for patients at a lower cost. I believe these trade-offs and providing solutions for them are very attractive.

EF: Since you have earned your client's trust, how do you help them make informed decisions?

FW: In the healthcare industry, data-driven decision-making is very crucial. Although we offer the fundamental data, it is crucial to generate new insights and improve forecasting and horizon scanning. This helps us to be more efficient. For many years, we have incorporated AI and machine learning into many of our client solutions as part of the usual delivery process for particular projects. In this respect, we have excellent traction with our pharmaceutical clients.

We also interact with hospitals, so care delivery organizations use data. For instance, we are collaborating with the University Hospital of Bielefeld's heart and diabetes center, Bad Oeyenhausen, as part of a landmark project. We are currently creating real-time support for heart surgeries using digital twins. Thus, with both their and our data, our technology, and AI models, we can provide the surgeon with real-time assistance to maximize the patient's outcome in terms of side effects, complications, and better rehabilitation.

Another example is the sick funds, which are under tremendous financial strain and are trying to cut costs. We digitize some of their processes for them. In Germany, we process hundreds of millions of invoices annually on their behalf, verifying that they are accurate and contain the correct deductions. We also streamline procedures. For instance, in collaboration with the biggest sick fund and a few other technology partners, we have digitized the midwives' administrative process so they can do everything digitally on-site while assisting the pregnant woman, eliminating the need for paper records. There are opportunities like this everywhere, and we are assisting the sick funds in using them to make better decisions and operate more effectively. We are concentrating on that since it is something that the healthcare system as a whole needs and requires – fresh concepts and new ideas by brave minds using technological progress.

EF: The financial and personnel sustainability of healthcare is crucial. How significant is it that IQVIA participates in discussions influencing the direction of healthcare?

FW: We made the strategic choice to broaden our scope beyond the pharmaceutical and life sciences industries because we think it is crucial to be included in the discussion beyond. The cost of the sick fund in Germany will rise by about 1.84 up to 4.4 percent per person, plus an additional 0.2 percent for care. For a total sick fund rise in 2025 of 2.5 % per person, which is a substantial increase. It is the biggest rise in a long time. Many of our clients and board members in the secretary health insurance division have told me that this is not sustainable. One of the reasons for this is that there are extraneous costs and expenses in the system that should not be borne by the insured members. They are funded by the solidarity system rather than by taxpayer dollars.

The finance issue is one of the big challenges, but the other challenge is the government determining spending priorities. The second is the rising cost of services, including employment costs for hospitals, stationary care facilities, etc. The largest factor is personal expense per patient in the aging society, which is a growing amount that needs to be controlled. As a result, other areas of the organization must become more efficient. This can be achieved through digital procedures and process improvements. Germany has some of the highest per capita spending for health in the world, but when it comes to the size of the difference between lifespan and healthy life, we do not have the best results per capita. If I look at big European countries like Spain, France, or Italy, it is not that different. This indicates that there is potential for improving the way we spend our funds, which means we need insights about what truly works and where funds are being spent that do not produce results. At IQVIA, we have experience and insights from other countries, but we also have the data and analytics to back up those opinions.

EF: Are there any particular partnerships or success stories you might provide that demonstrate how an IQVIA is advancing the country, genuinely propelling it to success, and fostering greater innovation?

FW: The renowned cardiac and diabetes center is one of the stories where we examine ways to improve cardiac procedures to have better results, which is

a very clear medical advantage. In this project, we employ those technologies for additional purposes, such as identifying rare diseases or assisting doctors in making treatment recommendations. Another example is that we are currently collaborating on the digitization of the administration, particularly in the non-hospital, non-pharmaceutical, and non-physician fields like physiotherapy and midwives. We process millions of invoices, and we look at automating those procedures by leveraging AI technologies in combination with OCR and NLP capabilities to extract information from the documents to make them easier to use and detect fraud.

Another example is the exchange of documents between the hospital and the specialist or treating physician; the documents come as PDF documents. To streamline the process, we have created an NLP-based application that automatically extracts all of the clinical information from those documents and enters it straight into the doctor's system. Physicians often spend too many hours reviewing such records; instead, they now simply obtain the information and can view it on the patient's end in the electronic health record.

. In rare disease cases, we inform patients that they might need to visit a doctor, or we create a digital patient journey for them, all while staying within legal limits of cause. We urge people to consult a doctor and employ social media-like technology to make healthcare more accessible. Additionally, this technology helps with the sometimes very difficult task of locating possible clinical trial volunteers. For this reason, we employ digital technology to help raise awareness, connect with healthcare professionals, and reach patients or potential patients.

EF: When you think back on your time at IQVIA, what are your proudest accomplishments to date, and what do you hope to achieve in the years to come?

FW: I've been in charge in Germany since 2010, so I've been in the position for 14 years total. In addition to always being engaging, it has always presented challenges in a constructive way. IQVIA was more focused on data and consulting when I joined but was not focused on technology or the larger healthcare sector. We faced many difficulties over the years, including COVID-19, but we also had our share of difficulties. In the end, the team is what I am most proud of. Over the years, I believe we have been able to keep a solid team. In my opinion, the last ten to fifteen years have seen the biggest shift in IQVIA Germany.

Being allowed to develop alongside the business has been a blessing. We currently have about 3500 employees in Germany and Austria, so I believe if I joined now, it would be considerably more difficult to come in and run the firm in this complex environment. It was about 300 when I started over, so the last ten years have seen a significant increase. The thing I am most proud of is how well-known IQVIA is in the industry. Rather than being restricted to the pharmaceutical industry, it is now viewed as a component of the larger solution. In my opinion, we have no idea where we'll be in five years. I never would have imagined the company's current state five years ago.

Prof. Dr. Ralf Huss

BioM Biotech Cluster Development GmbH
Managing Director

EF: How do you evaluate this year, and what are the main priorities for the BioM cluster in 2025?

RH: Our goal has always been to drive continuous innovation and successfully translate research into sustainable products, creating a long-term, self-sustaining market.

> Rather than relying solely on external innovation or waiting for others to acquire our advancements, we aim to build upon our strong foundation of excellent science and research. It is essential that we take discoveries from the bench to the market, ensuring their full potential is realized.

We recognize that the market has evolved. There is now less focus on oncology and increasing interest in neurodegeneration, longevity-related research, and metabolic disorders. Given this shift, we are leveraging our accumulated strengths to develop and manufacture most of our assets on our own. While regaining our previously externalized market may be unlikely, we must retain and strengthen our position rather than lose ground to other regions.

To address these priorities, we have strongly emphasized integrating AI and data-driven approaches into our strategy for this year. The recent Nobel Prizes in Chemistry and Physics have only reinforced our belief that AI will play a pivotal role in accelerating drug development and transforming how we create new medicines.

EF: How do you assess the region's approach to cutting-edge generative AI tools?

RH: There are different approaches to this. Startups and early-stage biotech innovators recognize the value of these technologies, but the challenge lies in accessing them. Implementing AI-driven tools requires extensive data and experience. Biopharma startups see the need, and as a cluster organization, we work to provide solutions.

However, it is not easy. The necessary infrastructure is complex, and regulatory frameworks have not yet been adopted. In silico trials, virtual control groups and AI-driven protein or mRNA synthesis remain largely untapped. There is significant potential, but convincing regulators to embrace faster preclinical development pathways is a key hurdle. While clinical development may not change immediately, AI could influence how trials are designed.

Another challenge we see is the gap between biotech and tech companies. Biopharma startups understand how AI can help solve their challenges, but many tech companies have solutions without clear problems to address. They develop algorithms, data curation tools, and cloud solutions but often struggle to apply them effectively in life sciences. Bridging this gap is essential for real progress.

EF: What factors make Bavaria an attractive biotech hub?

RH: BioM has been around for nearly 30 years, making it one of the first clusters in this field. Over these decades, we have built extensive experience and a strong network. Compared to other leading biotech hubs like Cambridge in the U.S. and the U.K., Bavaria stands out in several ways.

We have two top-tier universities—Ludwig-Maximilians-Universität (LMU) and the Technical University of Munich (TUM)—with over 100,000 students and more than 1,500 professors. These institutions offer strong medical, engineering, robotics, and IT programs, creating a rich talent pool. Additionally, Bavaria has a thriving mix of startups and established companies. Industry leaders such as Roche, AstraZeneca, Daiichi Sankyo, and MSD are expanding their presence, reinforcing the region's reputation as a biotech hub.

One challenge we are working to address is attracting more investors willing to support high-risk ventures. Given our cultural background, there has traditionally been a cautious approach to risk. However, this is changing. More major banks, private equity firms, and family offices are taking an interest in Bavaria's biotech sector.

EF: How do you evaluate BioM's role in shaping health policy and driving progress in this area?

RH: The German market is one of the most expensive and complex for drug approvals, making it difficult to introduce new medicines. This is why we emphasize developing new drugs from within our own portfolio. One of our key efforts is engaging with both the federal and state governments to push for regulatory changes that make it easier to establish and finance companies. The German GmbH (limited liability company) structure, for example, is often seen as a deterrent by investors due to its restrictions on investment, expansion, and exits. While it is easy for founders to set up, the lack of reporting requirements and investment limitations make it less attractive to global investors.

Another challenge is Germany's weak IPO landscape. The German stock exchange is hesitant to list small or nano-cap companies as they are considered too volatile and costly to trade. In contrast, markets like NASDAQ, Denmark, and the Netherlands are more open to smaller public companies, attracting greater investment. We are working to change this mindset by advocating for more flexibility in Germany's financial markets, particularly in Frankfurt and Munich, to encourage IPOs and attract private capital.

EF: Could you share some success stories from Bavaria?

RH: There are several success stories, but a few stand out. One is Tubulis, a company founded out of the Ludwig-Maximilians-Universität (LMU) Munich and the Leibniz-Institute for Molecular Pharmacology (FMP) Berlin. They have raised almost €200 million in venture capital and secured a milestone agreement with a major pharmaceutical company worth up to €1 billion. They specialize in antibody-drug conjugates and have developed a smart approach to designing technology that integrates antibodies, linkers, and payloads effectively. Tubulis started with BioM, participating in a BioM boot camp and receiving the BioM-coordinated m4 Award, which provided a EUR 500,000 grant as well as valuable visibility and community support.

Another example is CatalYm, a company focusing on immunotherapies, and iSPARC, which is currently conducting clinical trials at MD Anderson. These companies emerged from university research and benefited from the ecosystem in Bavaria.

While these success stories are promising, there is still room for growth. More cases like these could emerge if venture capitalists and public investors were more open to innovation and risk-taking. Public funding could play a crucial role in sharing risks, but currently, many public investment funds hesitate to take the lead. Encouraging them to do so would likely attract additional private investment.

Chapter 3

Pharma

Balancing Breakthroughs and Barriers

"The pace of innovation demands new thinking and a willingness to adapt. We are working with all stakeholders to enable this."
Alexandra Bishop, *Country President, Germany, AstraZeneca*

Pharmaceuticals in Germany: Between Innovation and Uncertainty

Germany has long stood at the center of Europe's pharmaceutical ecosystem, home to scientific excellence, robust manufacturing, and a well-established regulatory framework. But in 2025, the sector finds itself at a crossroads. On one hand, Germany continues to serve as a critical hub for clinical research, supply chain resilience, and the development of cutting-edge therapies. On the other hand, companies are facing mounting pressure from legislative reforms, pricing controls, and growing unpredictability in the reimbursement landscape.

At the center of this transformation is the evolving **National Pharma Strategy**, aimed at strengthening the country's pharmaceutical competitiveness. Yet many in the industry caution that frequent policy shifts and rushed implementation are threatening the very innovation the strategy seeks to promote.

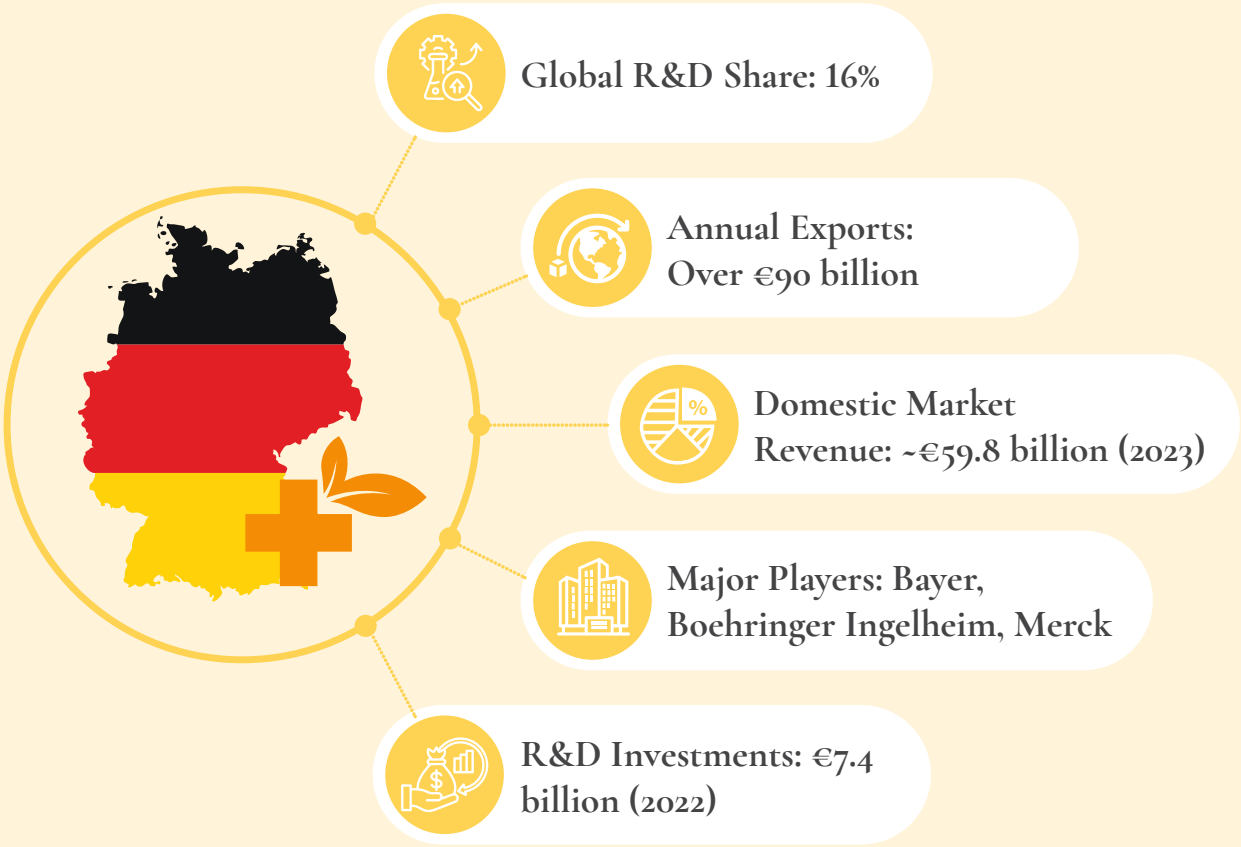
This chapter explores the key issues shaping the pharmaceutical sector in Germany today—from AMNOG reform and rare disease access to biosimilars, generics, digital transformation, and the future of advanced therapies. Drawing on insights from executives across biotech, big pharma, generics, and animal health, it captures a sector in motion—resilient, inventive, and calling for a clearer path forward.

The National Pharma Strategy: Turning Policy into Progress

After years of limited political focus on the pharmaceutical sector, Germany has finally introduced a **National Pharma Strategy**—a milestone welcomed across the industry. While sectors like automotive and chemicals have historically received more attention, this policy marks a deliberate effort to reposition pharmaceuticals as a strategic economic and scientific pillar for the country.

"From a broader perspective, we're finally happy to have a national pharma strategy. For many years, there wasn't a clear focus on the pharmaceutical

GERMANY'S PHARMACEUTICAL INDUSTRY AT A GLANCE



Source: https://altios.com/publication/the-pharmaceutical-industry-in-germany/

industry, while sectors like automotive and chemicals seemed to get more political attention." Says **Dr. Elmar Kroth,** Deputy General Manager, Pharma Deutschland

The strategy is widely seen as a turning point in how the federal government perceives the sector—no longer merely as a cost burden, but as a central driver of innovation and industrial competitiveness. *"Through their Pharma Strategy, the federal government highlighted eight distinct activities that will not only improve the state of our industry but also increase our competitiveness in terms of clinical research and prevention."* Claims **Manfred Heinzer**, Vice President & General Manager of Amgen Germany

Having moved away for a time to manage Australia and New Zealand before returning to Europe, **Urs Voegeli**, Managing Director, J&J Innovative Medicine, Germany, reflects on the development: "The *National Pharma Strategy was one of the most significant developments during my time away. It was a clear signal from the previous government, acknowledging the pharmaceutical industry as a critical sector for Germany and laying out plans to boost research, manufacturing, and access to innovation."*

For Elmar Kroth, the policy also validates the key role of Germany's pharmaceutical ecosystem: *"The pharmaceutical industry is one of the most thriving sectors in Germany, especially compared to the challenges the automotive industry has faced in recent years."* The National Pharma Strategy, first introduced in 2020 and now in its next implementation phase, aims to strengthen Germany's pharmaceutical ecosystem across R&D, manufacturing, and digital health. But its success depends on whether it translates into practical, reliable changes that support long-term planning.

Christiane von der Eltz, Managing Director of Berlin-Chemie Menarini, frames the issue clearly: *"We need a healthcare and pharmaceutical policy that is not dominated by short-term cost-saving measures, but one that sees the pharmaceutical industry as a strength and invests accordingly."* Many executives stress that Germany still has unique advantages to build upon. With its scientific base, skilled workforce, and industrial infrastructure, the country can remain a preferred launch market—if the right environment is in place.

As **Dr. Daniel Steiners**, General Manager, Roche Pharma Germany, notes: *"We want Germany to be a launch market again. But for that, we need a long-term orientation and clear framework conditions. Innovation must be welcomed and valued, not punished or discouraged."*

AMNOG Under the Microscope

Since its introduction in 2011, Germany's AMNOG system has served as the cornerstone of pricing and market access for innovative therapies. But with the pace of medical advancement accelerating, and novel treatment modalities emerging, leading pharmaceutical executives across the industry are warning that the framework must evolve—or risk holding back innovation and delaying patient access.

"Germany's current pricing and innovation assessment law, AMNOG, is 14 years old, but medical advancements have grown exponentially." Affirms **Urs Voegeli**, Managing Director, Johnson & Johnson Innovative Medicine Germany. Originally designed to ensure early access and cost-effectiveness, AMNOG now faces criticism for its rigidity, particularly in the evaluation of breakthrough and rare disease therapies. While the law's intention, to assess the added benefit of new medicines and negotiate prices accordingly, remains intact, many argue that its execution no longer reflects clinical reality. *"Medical progress has led to an erosion of the value-based core of the German AMNOG. We need to modernize the system to ensure that patients can rely on having early access to innovations when they are in need."* Concludes Voegeli.

This is echoed by **Alexandra Bishop**, Country President Germany, AstraZeneca: *"The German Pharmaceutical Market Reorganization Act (AMNOG), which was put into place in 2011, has not kept pace with advancements in science and needs to be modernized to ensure innovation reaches German patients."*

Manfred Heinzer, Vice President & General Manager of Amgen, reiterates the importance of an evolving framework, especially when it comes to next-generation treatments.*"Particularly for gene and cell therapy, the current AMNOG philosophy will have to evolve if patients in Germany are to benefit from early access to these innovations."*

From a rare disease perspective, the framework is especially problematic. Treatments often target small populations, lack standard comparators, or rely on novel clinical endpoints, elements that traditional HTA models struggle to accommodate. **Rüdiger Schulze**, Vice President & General Manager DACH, Ultragenyx, tells us, *"Since the inception of AMNOG, around 50 drugs have exited the German market due to unsustainable pricing. Beyond those that existed, additional drugs were never launched at all."* Schulze highlights how the problem is compounded by inconsistencies across Europe: *"For example, while the GBA in Germany ruled that one of our drugs had no advantage over its comparator, the French Haute Autorité de Santé issued a positive verdict with an ASMR rating of three. It's surprising to see HTA bodies coming to very different conclusions when analyzing the same medical evidence, and very unfortunate for the patients in Germany, particularly when minors."*

Toward a Science-Driven Future

Executives are calling for AMNOG reform rooted in clinical and scientific evidence. One key area is the acceptance of real-world evidence, especially when traditional randomized controlled trials are not feasible or ethical. *"In cases of high unmet medical need where no standard of care exists, traditional randomized controlled trials (RCTs)*

Reimagining Access – CSL Behring's Gene Therapy

At the start of 2023, **CSL Behring** reached a major milestone with the approval of the first gene therapy for hemophilia B from both the FDA and EMA. The one-time treatment offers the potential to improve patients' quality of life significantly. But with this scientific breakthrough comes a pressing challenge: how to make it accessible and sustainable within public healthcare systems.

"Our responsibility is not just to introduce innovation but to ensure it reaches patients in a financially sustainable way. This is particularly relevant when it comes to gene therapy." **Christian Wieszner, Managing Director, VP DACH Cluster, CSL Behring**

Unlike traditional treatments, which involve lifelong and often costly care, gene therapies present a new model of care—and a new financial paradigm. Christian highlights that traditional reimbursement structures, built around chronic, recurring therapies, may not be suited to one-time treatments with high upfront costs. *"However, the financial model for such treatments is different—it presents an upfront cost rather than ongoing payments, which can put pressure on healthcare budgets."*

In response, CSL Behring worked with health authorities to develop novel reimbursement pathways. *"Our proposal is a success-based annual payment model, which ensures predictable costs and aligns with the price of existing long-term treatments. Under this model, reimbursement would be spread out over several years, only continuing if the treatment proves successful."*

This value-based approach shifts the risk and ensures patients benefit only when the therapy delivers the intended outcomes. Importantly, it also allows healthcare systems to manage costs in a more predictable and incremental way. *"We are committed to making this treatment available to the patients who need it most, through the healthcare community in a way that is, as said before, sustainable for the health system as well."*

With regulatory bodies expecting up to 20 gene therapy approvals per year in the near future, Wieszner believes public systems must adapt rapidly: *"Healthcare systems, especially in Western countries, must prepare for both the benefits and financial challenges that come with these innovations."*

In April 2025, CSL Behring's negotiations with German health authorities concluded successfully. A first-of-its-kind outcomes-based agreement was reached, directly tied to clinical performance. On July 1, 2025, the first patient in Germany received treatment under this model, marking not only a significant milestone for CSL Behring but a new era in sustainable access to advanced gene therapies.

INNOVATION
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Every day, our sole focus is to deliver on our promise to patients. To achieve that, we leverage our unique talents to develop and deliver innovative medicines that help people with serious and life-threatening conditions live full lives and protect the health of communities around the world. Learn more at **CSL.com/Vita**.

Driven by Our Promise

CSL Behring

may not always be feasible or even ethical… Our position is clear: AMNOG reform should be driven by science and evidence." Says **Urs Voegeli**.

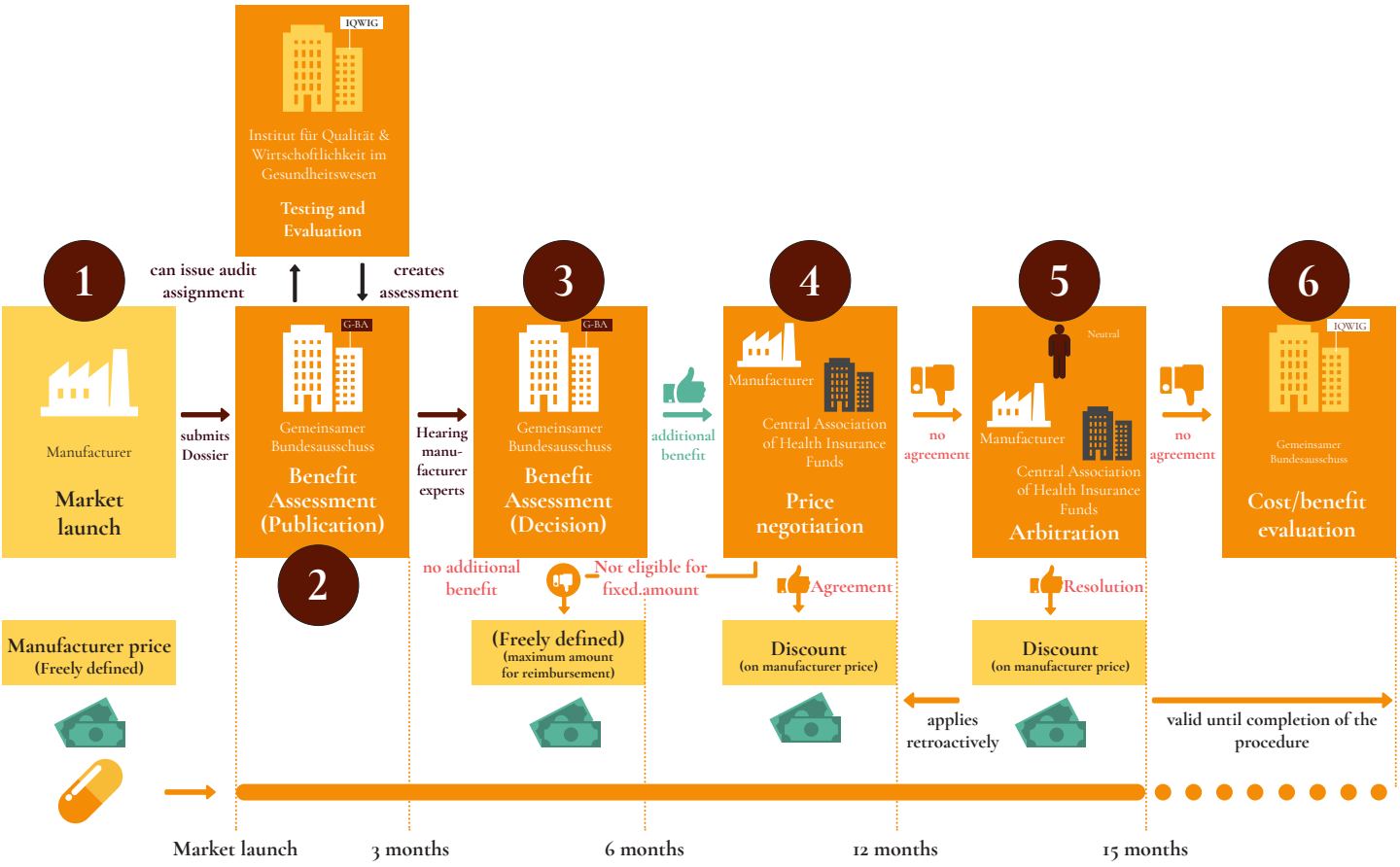
Rüdiger Schulze points out that a more flexible framework would allow for tailored agreements with payers: *"Greater flexibility in the system would allow us to reach adaptable agreements with payers, acknowledging the specific needs of individual patients affected by rare diseases."*

Beyond the impact on access, the AMNOG system—if left unchanged—may jeopardize Germany's role as a launch market and a leader in biomedical innovation. *"While it did save some money to some extent, in the short term, it sent devastating signals and made innovation much more difficult, creating a hostile and constrictive environment for pharmaceutical companies in Germany,"* claims **Manfred Heinzer.**

Realigning for the Future

While the German government has taken initial steps, the consensus among leaders is clear: AMNOG must be reformed to reflect today's science and tomorrow's therapeutic possibilities. *"We need predictability, clear and stable guidelines on evidence requirements, comparator treatments, and clinical trials that are fit for purpose. This is where we strongly advocate for reform."* Concludes **Voegeli.**

Without change, executives warn, Germany could lose its reputation as a first-launch market and innovation hub. With reform, however, AMNOG could once again become a model for value-based, evidence-driven healthcare access, benefiting both patients and progress.



Source: Bundesministerium für Gesundheit

Zoetis and the Future of Animal Health

While the pharmaceutical conversation often centers on human medicine, animal health is an essential and growing pillar of healthcare innovation. At the forefront is **Zoetis**, the world's largest animal health company, which is redefining standards across pet care, livestock medicine, diagnostics, and AI-powered tools.

Julia von Gablenz, Regional President for Europe and the Middle East, views Zoetis not only as a scientific leader but also as a purpose-driven organization committed to long-term, sustainable impact. *"In recent years, Zoetis has cemented its position as the global leader in animal health, and the opportunities ahead remain promising. Germany is the fifth-largest animal health market in the world. Notably, we have achieved market leadership in Germany in early 2023 – a milestone we are very proud of."*

Innovation in companion animal health is one of Zoetis' fastest-growing areas. The company has invested deeply in therapies for chronic diseases like pain, kidney failure, and cancer in cats and dogs—areas often under-addressed in traditional veterinary care. *"Here, we see many unmet medical needs. In areas such as renal, cardiology, pain, and oncology, we are investing heavily in research and development. Our monoclonal antibodies in these areas have transformed the quality of life for pets and their owners, and we are committed to further expansion."*

Zoetis also plays a critical role in livestock care, helping producers meet the growing demands of global food systems while prioritizing animal welfare and sustainability. Innovation is driven not just by vaccines and medicines, but also by predictive tools and integrated diagnostics. *"We are dedicated to continued investment in this area and to supporting farmers through a comprehensive approach focusing on disease prediction, prevention, diagnosis, and treatment. Sustainability also plays a key role here, with initiatives like improving farm management practices and launching innovative vaccines, including a first-of-its-kind cattle vaccine against respiratory diseases."*

Technology is a major differentiator. From AI-powered diagnostic tools like Vetscan Imagyst to digital platforms supporting veterinarians and customers, Zoetis is leading the digitization of animal healthcare. *"AI is transforming diagnostics, treatment plans, and patient monitoring. These technologies enable faster and more accurate disease detection, personalized treatment plans, and predictive analytics for better health outcomes."*

With a strong foundation in innovation, purpose, and digital transformation, Zoetis is expanding what it means to lead in animal health, not only as a business, but as a partner in a broader, interconnected healthcare ecosystem.

Generics Under Pressure: Securing Access in a Shifting Landscape

Generic medicines are the foundation of Germany's healthcare system, quietly delivering accessible treatments to millions while relieving budgetary pressure on payers. Yet the companies producing these essential drugs are sounding the alarm. From untenable price erosion and regulatory burden to fragile supply chains, the generics sector is under strain, and its future in Germany may no longer be guaranteed.

"Generics account for 80% of all prescribed medicines in Germany but only for 8% of the total pharmaceutical spending by statutory health insurance." States **Josip Meštrović**, General Manager, Zentiva Germany

For **Meštrović**, this is a statistic that tells two stories: one of efficiency and contribution, and another of imbalance. The public expectation for low-cost medicine has been institutionalized in policy, most notably through Germany's tender system, where contracts are awarded largely based on the lowest possible price. *"The lowest price still wins, regardless of where a company manufactures, the quality standards it upholds, or whether it invests in green production."*

Thomas Weigold, Country President Germany of Sandoz, describes the tender model as a system that worked well for years but is no longer fit for purpose. The risks it creates—product shortages, market exits, and collapsing supply resilience—are becoming visible. *"This is one of the biggest challenges we're currently dealing with. At some point, we have to stop basing everything on price alone."*

Andreas Burkhardt, General Manager Germany at Teva Pharmaceuticals and Chair of ProGenerika, agrees that structural financial pressure has intensified in recent years. *"We are facing serious economic pressure from rising costs, reimbursement cuts, and stricter requirements for supply and availability."*

A Vision for Reform

All three executives stress the urgent need to reform the current model. Proposals include multi-winner tenders, stronger recognition of quality and sustainability, and systems to better anticipate and manage shortages. This is encapsulated in the following quotes:

"The race to the bottom must stop when a molecule reaches a critical point." **Thomas Weigold,** Sandoz

"We need a new approach prioritizing quality, environmental responsibility, and long-term supply chain stability." **Josip Meštrović**, Zentiva

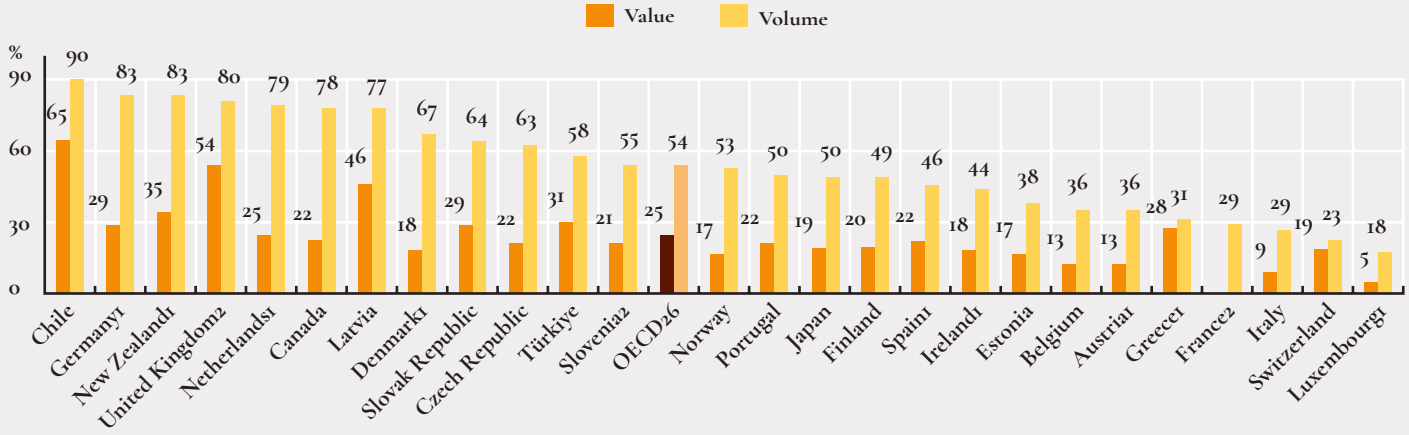
"We advocate for realistic reforms that reflect the true value of generics and biosimilars." **Andreas Burkhardt,** Teva

A Public Good Worth Protecting

For generics companies, this is not just a business challenge, but a societal one. Generics ensure universal access, underpin health system sustainability, and serve as a public good. That role must be protected through a policy that matches the sector's values.

"We're not just a strategic partner in the healthcare system. We also have a responsibility," confirms **Weigold**. As Germany navigates rising healthcare costs and global uncertainty, the future of generics should not be left to market forces alone. It is time, these leaders

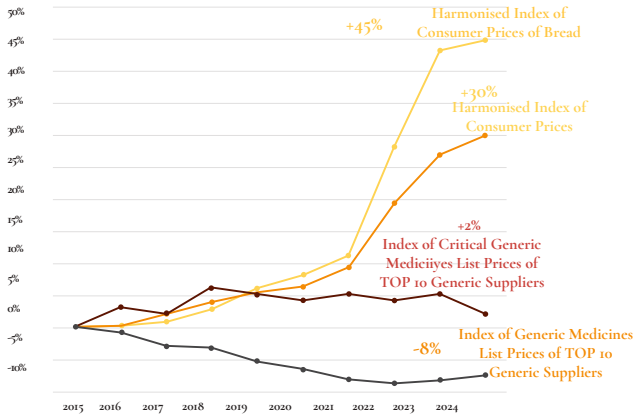
SHARE OF GENERICS IN THE TOTAL PHARMACEUTICAL MARKET



Source: OECD Health Statistics 2023.

A Clean Water Directive with Cloudy Consequences

The UWWTD is by far the biggest threat to our sector because our companies cannot legally increase prices to offset EPR fees in Membev. This graph shows the differences between our sector and other industrial sectors that operate in free pricing markets. Whereas industrial goods or commodity prices have increased between 30-45%, generic medicine prices have decreased over the last ten years.



Source: https://www.medicinesforeurope.com/wp-content/uploads/2025/05/Case-for-UWWTD-in-the-simplification-omnibus-03192025.pdf

As environmental regulations tighten across Europe, the pharmaceutical industry is preparing for the wide-ranging implications of the **Urban Wastewater Treatment Directive (UWWTD)**, a well-intentioned initiative that may carry unintended consequences for patient access and medicine supply.

Josip Meštrović, General Manager Germany & Switzerland at Zentiva, has been vocal about the risks posed by the Directive's current implementation framework, which shifts the financial burden of wastewater treatment directly onto pharmaceutical manufacturers, regardless of where emissions originate. *"The Directive shifts the cost of water treatment processes onto us, along with the cosmetics industry, which would cost us millions and be an unreasonable burden."*

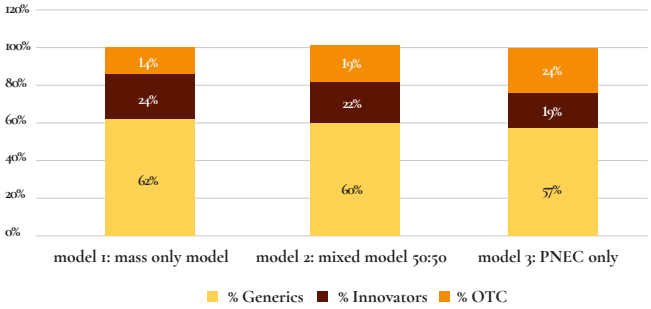
Zentiva has taken a rare step in response: challenging the regulation at the European level. *"The UWWTD will have significant consequences in Germany and Europe, potentially jeopardizing millions of people's access to affordable medicines. In response, Zentiva has taken a strong position by filing a legal case with the European Court of Justice."*

The concern, **Meštrović** explains, is not about rejecting environmental responsibility, but rather about fairness and feasibility, particularly for high-volume, low-margin industries like generics.*"To be clear, we fully support clean water initiatives and the Green Deal. Safe water is crucial for life and medicine production, and we're not opposing environmental responsibility. However, the way this Directive is being implemented is simply discriminatory. We're willing to pay our share, but this feels more like an added tax that disproportionately affects the generics industry due to the sheer volume we handle."*

In a context where generics already account for the majority of prescriptions but only a fraction of pharmaceutical spending, additional financial and regulatory strain could further destabilize European manufacturing and supply chains. *"This Directive seriously threatens our viability as a Europe-focused generics company. It creates an unacceptable risk to millions of people by potentially leading to medicine shortages, leaving behind our patients who depend on essential medicines every day."*

With the legal challenge now moving forward, the broader generics industry will be watching closely. At stake is more than environmental compliance—it is the balance between sustainability and access, between policy ambition and operational reality.

GENERICS ARE ESTIMATED TO BE A LARGE SHARE OF TOTAL FEES



Source: https://www.medicinesforeurope.com/wp-content/uploads/2025/05/Case-for-UWWTD-in-the-simplification-omnibus-03192025.pdf?utm_source=chatgpt.com

Teva's Deep Roots and Long View in Germany

As one of the world's largest generic and specialty pharmaceutical companies, **Teva** sees Germany not just as a key market, but as a cornerstone of its global strategy. The country ranks as Teva's second-largest market after the United States and plays a critical role in its manufacturing, talent, and innovation footprint.

"Germany is strategically significant for Teva due to several factors. First, in terms of pure numbers, Germany is the fourth-largest pharmaceutical market globally and the second-largest market for Teva after the U.S.," says **Andreas Burkhardt**, SVP General Manager, Teva Germany.

Teva's presence in Germany was solidified in 2010 with the acquisition of Ratiopharm, which elevated the company from a fragmented European player to a market leader in generics. Today, its site in Ulm is a core part of its global manufacturing network.

"Teva has established complex production capabilities in Germany, particularly in Ulm, which is home to facilities producing solids, supplements, creams, and ointments. This site also houses the largest sterile nasal spray manufacturing unit within the Teva network, showcasing the advanced technologies and expertise concentrated here."

This commitment to German production is not just a legacy, it's a strategic move. Teva recently chose Germany for a new biopharmaceutical production facility. Burkhardt continues, *"Despite other countries offering significant tax benefits, the decision clearly favored Germany. The rationale included the availability of a highly educated workforce and the advantage of being part of a biopharma cluster stretching from Germany to Milan."*

Whether through industrial investment, organizational reform, or a hybrid generics-innovator strategy, Teva's approach to Germany is long-term and deeply embedded. In a challenging environment, the company is doubling down, not stepping back.

Local Legends: Germany's Homegrown Pharma Champions

In a pharmaceutical landscape dominated by multinational giants and cross-border consolidation, Germany's family-owned pharmaceutical companies continue to carve a different path—one built on heritage, independence, and long-term thinking. Klosterfrau and MEDICE are two such success stories: locally rooted, strategically agile, and evolving rapidly while staying true to who they are.

Klosterfrau: A Modern Turnaround with Historic Roots

Founded over two centuries ago, Klosterfrau is one of the oldest and most recognizable names in German self-medication. But while its identity is rooted in tradition, its current trajectory is one of reinvention.

"It is always amusing to frame it as a startup founded by a woman 200 years ago. But it's true. Maria Clementine Martin began by producing and selling remedies, laying the foundation for what would become Klosterfrau." Says **Dr. Stefan Koch**, CEO, Klosterfrau-Gruppe

When Dr. Koch took the reins, his strategy wasn't to pursue rapid globalization or become a pharmaceutical giant, but rather to re-center the company around its strengths and identity. *"Previously, there was an effort to transform Klosterfrau into a large, publicly traded, globally operating company. However, that approach did not align with who we truly are."*

Instead, the company focused on agility, brand revitalization, and pipeline growth. *"This year alone, we will launch seven or eight new products, including pain gels and omega-3 products,"* informs Stefan. Operational investment is a cornerstone of this shift. Klosterfrau is upgrading production across its facilities in Germany, Austria, and Switzerland, with a strong emphasis on sustainability.

"We are investing a lot of money in our production sites in Berlin and Cologne, as well as in Austria and Switzerland, particularly in machinery and process optimization. In Cologne, we aim to make our site CO_2 neutral by 2030."

MEDICE: Innovation with a Family Identity

For **Dr. Richard Ammer**, CEO at MEDICE, the company's foundation is deeply rooted in post-war Germany, and so is its transformation. *"MEDICE was founded in 1949 by my wife's grandfather Gustav Pütter, who entered the field of medicine after the British allies, following World War II, encouraged him to distribute antibiotics from Bayer Leverkusen in rural areas."*

Since then, the company has remained family-led, with Ammer and his wife Katja representing the third generation. *"Katja first gained experience in big pharma for training purposes and then officially joined MEDICE in 2001. I followed in 2003, and together, we have been managing owners for nearly two decades."*

MEDICE earned a leadership position in ADHD care through its development of modified-release capsules. *"With the introduction of modified-release capsules, parents retained control over the medication, eliminating the need for children—who often struggle with self-organization—to take a second dose during school hours. This advancement, which ensures coverage throughout the school day, has been a breakthrough in ADHD pharmacotherapy and has helped us secure a market-leading position in Europe."*

The company now operates across a diverse portfolio that spans prescription medicines, primary care, and consumer health, but all production remains in Germany. *"A defining aspect of our company is full integration—we conduct our own research, clinical and analytical development, and manufacturing. Our products are produced entirely in Germany at two sites."*

Ammer has also driven MEDICE into digital health, with new applications supporting mental health, ADHD, and chronic conditions. *"We are in the launch phase of introducing evidence-based digital applications with clinical validation."*

Sustainability is central to the MEDICE philosophy, with three companies launched to lead the charge. *"We have established three companies dedicated to sustainability. Sustainable4U is the first company, and it ensures that all marketing materials and events meet sustainability criteria... Friendship is the second company, and it provides employees and customers with ecologically sourced, seasonal food. The third company, Green Guide, consults with hospitals and senior living facilities to optimize food use, reduce waste, and reinvest savings into higher-quality ingredients."* Ammer sums up his leadership philosophy with a forward-looking mindset: *"My philosophy has always been about keeping the fire burning rather than just preserving the ashes of tradition."*

Championing Rare Diseases in Germany: Innovation, Access, and a Collaborative Future

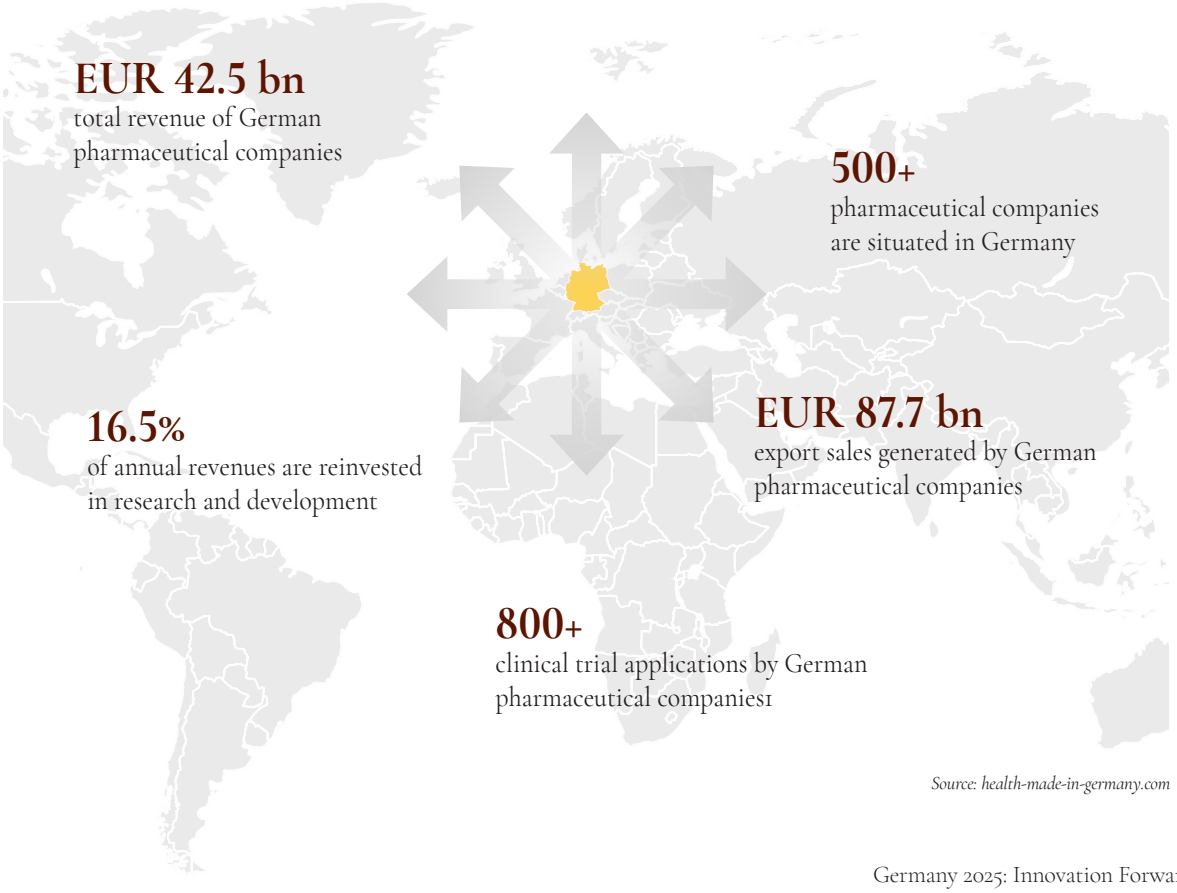
Germany continues to serve as a cornerstone for rare disease innovation in Europe, with leading companies pushing the boundaries of diagnostics, access, and policy engagement. Yet significant challenges remain, especially around early diagnosis, system fragmentation, and ensuring equitable access to high-cost therapies.

For **Michael Kickuth**, General Manager at Recordati Rare Diseases DACH, the time it takes to diagnose is among the most pressing issues: *"In Cushing's disease, the time from symptom onset to diagnosis in Germany is twice as long as in other parts of Europe or the U.S."* To shorten that timeline, the company is building innovative support tools for clinicians: *"We are integrating digital red flags into practice software that alerts physicians if a patient's symptoms align with rare disease criteria."* But he adds: *"There is no one-size-fits-all solution... The key is synchronization—getting all the pieces to work in harmony."*

Rüdiger Schulze, *Vice President and General Manager DACH at Ultragenyx*, shares the concern about diagnostic delays and the heavy toll on patients. *"Despite the advances in big data analysis and artificial intelligence, the time to establish the right diagnosis is still much too long – many patients still go through a revolving door of specialists without getting real answers."* He sees significant promise in early screening, particularly through genetic testing: *"With generalized genetic newborn screening, finding these patients before the emergence of irreversible symptoms seems much more likely."*

Andrea Passalacqua, *Vice President and General Manager Germany at Alexion, AstraZeneca Rare Disease*, highlights Germany's historically strong reimbursement model: *"One key factor is that once a medicine receives EMA approval, it becomes immediately available to patients, with only minimal administrative steps required."* Still, he points out, access starts with awareness. *"A major part of this involves education – raising awareness that certain rare diseases exist, how they can be diagnosed, and what testing methods are available, whether genetic or biology-based."* He sees collaboration as central to any long-term improvement: *"We believe it is our responsibility to partner with stakeholders across the system—including physicians, patient organizations, payers, and policymakers—to bring about positive change."*

Ultimately, leaders believe rare disease care demands not just science, but dedication at every level.



Source: health-made-in-germany.com

Dr. Daniel Steiners

Roche
Chief Executive Officer, Roche Pharma AG

EF: What attracted you to Roche, and what are your current priorities?

DS: What drives us in the industry is ensuring patients have timely access to the latest innovations and medical advancements. Achieving this requires a supportive policy environment that values and embraces innovation in all its forms, whether incremental progress or breakthrough treatments.

What is new in my role at Roche is the different portfolio I now manage. Roche has a long legacy, especially in oncology, but we are also delving into gene therapy, which is incredibly exciting. Another aspect I am passionate about is fostering a culture rooted in integrity, courage, and passion. It is becoming increasingly important for organizations to harness data and technology across all levels to shape the future of healthcare. This goes beyond the pharmaceutical value chain and involves collaborating with others in the ecosystem to maximize the potential of data.

In terms of Germany's position, I still envision it maintaining its leadership role globally.

> "Germany has always been a powerhouse for Roche, and that continues to be our aspiration."

EF: How has the national pharmaceutical strategy impacted the innovation and competitiveness landscape, and what role are Roche and the broader industry playing in shaping this system?

DS: The pharmaceutical industry operates with long innovation cycles and substantial investment, often ranging from €1 billion to €1.5 billion per product, with a 90% failure rate. It can take up to 13 to 15 years to bring a product to market, which in itself is a daunting process. However, the challenge becomes even greater when the policy frameworks we operate under are changed unpredictably. Unlike other industries that may seek subsidies, we simply ask for a stable environment that provides the security needed for long-term planning.

What has changed, though, is that the government has recognized the pharmaceutical industry as a key driver for growth and a leading industry. The goal is to retain and expand the industry, as Germany was once known as the "pharmacy of the world" but has since lost that standing. The focus is on keeping the existing infrastructure intact and fostering its growth.

Over the last two years, both the industry and Roche have demonstrated a willingness to invest. At the Pharma Summit held in late 2023, representatives from pharmaceutical companies, academic research institutions like the Helmholtz Institute, and industry associations gathered to discuss this issue. The government expressed its understanding that healthcare policy is inherently linked to industry and economic policy.

In response, they began drafting legislation aimed at strengthening Germany's position, particularly in clinical research. One of the first steps in this direction was the Medical Research Law, which aims to restore Germany's competitiveness in global clinical trials. This law addresses bureaucratic roadblocks and introduces incentives for pharmaceutical companies that conduct a significant portion of their trials in Germany, such as exemptions from certain pricing regulations.

Other legislative measures are also being considered, including the use of medical data for scientific research. Overall, these developments show positive intent and a commitment to making Germany a more attractive environment for pharmaceutical research and innovation.

EF: Can you share some insights into Germany's role on the global stage, particularly with its various sites, new gene therapies, and research centers? What can we expect from these and upcoming investments?

DS: Roche has been embedded in Germany for as long as the company itself has existed—127 years. The first German subsidiary was founded alongside Roche's establishment in Switzerland, and the company has since grown its presence through both organic investments and strategic acquisitions, e.g. in Mannheim.

Today, Germany remains one of Roche's largest global locations, with approximately 18,000 employees. The country plays a central role in managing the full value chain for both pharmaceuticals and diagnostics, including R&D and commercialization. Specifically, Roche operates sites focused on protein design and production, diagnostic reagents and tests, and, most recently, gene therapies. Additionally, the company is integrating artificial intelligence and data-driven projects into R&D efforts.

Roche's investment volume in expanding our production, research, and administrative facilities in Germany has totaled over 3 billion euros in the past five years, and the future will largely depend on continued support from the German government to improve the policy frameworks. With ongoing investment, Roche is poised to further expand its footprint in Germany, contributing to the country's growth as a hub for the pharmaceutical industry.

EF: Looking at the pipeline from a broader perspective, which areas of upcoming treatments are you most excited about, and which do you believe will have a significant impact on healthcare?

DS: Recently, we conducted a review of our key focus areas, and there is a staggering number I would like to share. Roche currently has 72 new molecules in R&D across a broad range of diseases. The key therapeutic areas include oncology, hematology, neurology, immunology , cardiovascular and metabolic disorders, and ophthalmology—just on the pharmaceutical side.

In diagnostics, we are setting new standards with our mass spectrometry technology. There is a lot happening, and what excites me is how some of these areas are nicely interconnected. For instance, with Alzheimer's disease, we have a test for early detection, which is crucial when considering new treatments. We also have a product in the pipeline with brain shuttle technology, showing promising early clinical trial results. If this treatment reaches the market, it could make a real difference for patients and families affected by Alzheimer's, a disease that has historically been difficult to treat.

Additionally, we are also committed to advancing treatments for infectious diseases, especially antibiotics. Many companies have exited this area, but Roche continues to invest, as we believe it is crucial for humanity to have new antibiotics, even if the economic incentives are challenging. From antibiotics to cell and gene therapies, Roche's pipeline spans a wide range, and that diversity is what truly excites me.

EF: Given Roche's significant footprint, how does it attract the best individuals but also keep them engaged and committed to the company over the long term?

DS: The key point here is that, while this applies to many companies, Roche stands out due to its long legacy and culture of innovation and purpose. Our mission, "doing now what patients need next," resonates deeply with people. It is purpose-driven and focuses on improving global health through groundbreaking pharmaceuticals—not just in oncology but also in areas like anti-infectives and other therapeutic research. Roche believes in creating a triple win—benefiting patients, society, and the company itself—by continually advancing innovation.

EF: What changes or innovations would you like to see at Roche over the next five years?

DS: For a long time, Roche's mantra has been "follow the science," which served us well. However, given the increasing complexity of the technologies, diseases, and competitive landscape, we must focus our efforts more strategically.

What Thomas Schineker, Roche's CEO, is doing is introducing a set of criteria to help align the R&D organization. This ensures we focus on areas where we can apply the highest level of knowledge to develop first- or best-in-class medicines that also have a clear path to value.

I am also excited to work with the team to ensure that technology will transform every part of our value chain, especially in how we interact with healthcare professionals. We need to ensure that they have all the information they need to make the best decisions for their patients.

We want to move to more targeted treatments, improving our success rate with every patient. The potential is vast—there are way over 10,000 known diseases, and only half of them have treatments, many of which do not fully cure the disease

AI will play a crucial role in all of this. The complexity of our research is enormous, with thousands of cell types, 20,000 genes, and countless combinations. It is impossible to process all of this in a lab without computing power, which is why we have partnered with NVIDIA. This strategic partnership and others ensure we have the computing power necessary for advanced research, including the cutting-edge technology required for what we call "lap in the loop."

Alexandra Bishop

AstraZeneca
Country President, Germany

EF: What can we expect from AstraZeneca in Germany in 2025?

AB: This year, the focus is on the future. Overall, we expect to launch eight new medicines or new indications, which will bring significant benefits to patients in Germany. Everything we're working on aims to improve patient outcomes, and further scientific knowledge and innovation, thereby contributing to a stronger healthcare system. AstraZeneca, is one of the fastest-growing pharma companies, and we're solidly in the top 5 Pharma in Germany.

The priority is to ensure that German patients have access to the best new treatments and that Germany continues to be an attractive country for innovation, from clinical research to market. The new government has a great opportunity to ensure Germany is at the forefront.

EF: What do you hope to see from the new government's perspective on pharma?

AB: What we're already starting to see in the new coalition, is a strong confirmation that pharma is recognized as a strategic industry for healthcare and a positive contributor to Germany's future competitiveness. It is good to see the clear acknowledgement that current frameworks need to be reviewed to ensure continued access to innovative medicines for patients in the future.

What needs to be improved, though, is how the sustainable financing of healthcare will be addressed. We need a clear plan to ensure sustainable healthcare financing, which also ties into the frameworks: what we reward, protect, and how we fund innovation for the future. Tackling bureaucracy and complexity more seriously, which costs a significant amount of time and resources, and boosting digitalization will help.

EF: Could you tell us about the value that Germany brings beyond its market size, your research footprint, and your plans to expand your research footprint in Germany?

AB: Germany is the fourth-largest market in the world, and the leading European market, so it's incredibly important. What Germany brings to the table is significant: a highly skilled workforce, as well as some of the top healthcare institutions, academic hospitals, and researchers, offering a very high level of expertise.

We are currently one of the leading companies in clinical research in Germany. We want to do even more.

> "There is a clear opportunity to not just attract investments in this area but to ensure Germany stays at the forefront of innovation and research."

Two things hindering progress: One is the bureaucracy that delays clinical trials in Germany vs other European markets, which has recently improved, but still has more to do. Two is the prospective outlook: the German Pharmaceutical Market Reorganization Act (AMNOG), which was put into place in 2011, has not kept pace with advancements in science and needs to be modernized to ensure innovation reaches German patients.

The foundations are good. However, the pace of innovation demands new thinking and a willingness to adapt. We are hopeful and working with all stakeholders to enable this.

EF: How is your portfolio balanced in Germany, and what kind of upcoming treatments and areas are you excited about in the future?

AB: This industry hasn't had a more exciting time, especially at AstraZeneca. While we have a broad portfolio, we also have a clear strategic focus. At the highest level, we concentrate on three main areas: Biopharma, Oncology, and Rare Diseases. Within these divisions, we've narrowed in on specific therapeutic areas where we aim to lead and have built real depth, allowing us to deliver products both now and in the future. Our ambition is to launch 20 new molecular entities by 2030. That's just the new molecular entities (NMEs). Each could have multiple indications beyond the initial approval. We are currently standing at nine NMEs that have been launched globally.

Regarding focus areas, there are so many exciting developments that it's hard to pick just a few. In oncology, for instance, we're aiming not only to become number one but to eliminate cancer as a cause of death. We're active across key areas from Hematology, lung, breast, gastric, and women's cancers, applying multiple treatment modalities to improve patient outcomes, whether alone or in combination. One common theme in oncology and chronic diseases is that the earlier we intervene, the better the outcomes for patients. We're approaching these challenges from every angle.

We also strongly focus on improving patient outcomes in cardiovascular, renal, and metabolic. In particular, we are advancing therapies for heart failure and have renewed attention on hypertension, which has been somewhat overlooked in recent years. We're also focusing on dyslipidemia, a renal product portfolio, and we are moving into the weight management space. On the respiratory side, we continue focusing on improving outcomes in Asthma and COPD, with multiple new molecules in development, and we are expanding into Immunology.

Our newer focus area is vaccines and immune therapies, with a focus on serious bacterial infectious diseases and immunocompromised patients, with several molecules in development. Our work spans a range of targets, including RSV, HPV, and influenza.

EF: The timing of the treatment is crucial. Can you expand on how AstraZeneca is focusing on that?

AB: In the case of chronic diseases, many are preventable or can be significantly delayed with early diagnosis and effective intervention/treatment. Conditions such as chronic kidney disease, heart failure, diabetes, hypertension, and dyslipidemia, which are future portfolio focus areas for us, can all benefit from earlier management. Catching and treating illnesses early can help prevent other health issues and improve patient outcomes.

We cannot achieve this alone, however; it requires strong partnerships with healthcare systems and a shared recognition of the importance of early screening, diagnosis, and preventative care. The healthier we can keep individuals, the more they can contribute to society by working, paying taxes, and supporting their families. It's important to remember that when one person falls seriously ill, the impact often extends to family members who carry a heavy emotional and practical burden. At AstraZeneca, we work with partners such as clinicians and institutions, societies, and also insurers, on real-world data to demonstrate the gaps and opportunities, and then with the same to recommend any improvements.

EF: What is AstraZeneca's perspective on the opportunity that data and digitalization represent in Germany?

AB: Data and digitalization are one of the untapped opportunities in Germany that could significantly help reduce costs and drive insights into better care or even inefficient care.

Currently, less than 10% of patient data is structured in a way that makes it truly usable. This presents an enormous opportunity to digitize data, better understand what is working and what is not, create efficiencies, improve quality of

care and outcomes, and ultimately free up funding for the healthcare system, forming a positive cycle. An analysis by McKinsey shows that more digital solutions in the healthcare system could reduce costs by 42 billion euros**.** Moreover, digitization could also help in clinical trial recruitment, encouraging more innovation in Germany.

EF: What have been some of the strategies that you have employed to attract and retain top talent in such a competitive market?

AB: Attracting and retaining talent for us is fundamentally driven by purpose. We are a bold and courageous company with ambitious goals. Our AstraZeneca Germany "Made for More" campaign is a concept born from deep internal reflection a few years ago. It highlights our belief that we deliver a positive, meaningful impact. This ethos runs through everything we do, including our sustainability efforts.

Christian Wieszner

CSL Behring
Managing Director And Vice President DACH Cluster

EF: Can you share your mission and vision when starting this role?

CW: Whenever I step into a new role, I always ask myself: How can I guide my team to make a lasting impact? Returning to Germany after spending most of my career abroad has been an interesting experience. Germany is facing challenges, but it also presents significant opportunities. One of my main goals has been to position Germany at the forefront of bringing CSL's innovations to patients. That means improving access and reducing barriers in a way that benefits everyone—patients, the public healthcare system, and CSL.

> "Our responsibility is not just to introduce innovation but to ensure it reaches patients in a financially sustainable way."

This is particularly relevant when it comes to gene therapy. Beyond that, I am focused on strengthening CSL's presence in Germany, building a high-performing team, and creating an inclusive and diverse culture that drives innovation, agility, and success.

EF: What can we expect from CSL Behring in Germany in 2025, and what are your key priorities?

CW: Every year brings new opportunities and challenges, and this one is no different. In Germany, the political landscape is shifting, with elections happening sooner than expected. At the same time, the healthcare system is evolving and making progress but also facing new obstacles. From a company perspective, we are preparing to launch two new products. Europe, and Germany in particular, have become key players in the plasma industry. While innovative products like monoclonal antibodies and gene therapy are exciting advancements, the foundation of our business remains plasma.

Germany plays a leading role in this field, supported by highly specialized manufacturers and providers responsible for plasma collection and developing innovative plasma-based treatments. CSL has a strong presence in Germany, especially in Marburg, where we have a major production footprint. It is crucial that decision-makers, policymakers, and the public at large understand the significance of the production of plasma derivatives. Recognizing the unique nature of this industry is the first step in ensuring its continued success and advancement.

EF: Can you provide an overview of your current portfolio and how you expect it to evolve in the coming years?

CW: CSL operates through three main divisions: CSL Behring, which focuses on therapies for serious medical conditions; CSL Seqirus, which is responsible for influenza vaccines; and CSL Vifor. In total, the company employs about 32,000 people worldwide. At CSL Behring, our mission is to not only develop innovative therapies but to ensure they reach the patients who need them most. We focus on key therapeutic areas, including immunology, hematology, cardiovascular and metabolic diseases, respiratory conditions, and transplants. To support this, we have built three core scientific platforms: plasma fractionation, which is the foundation of our work; recombinant protein therapies, especially for hemophilia; and new, cutting-edge approaches like cell and gene therapy.

Germany plays a crucial role in our research and development efforts. Beyond commercial operations, which I oversee, we also have a strong R&D presence, backed by over $5 billion in investment over the past five years. This commitment to innovation is what allows us to continue developing life-saving treatments. Looking ahead, we are expanding geographically—not just in Latin America and Asia-Pacific but also within Europe. However, just as important as growing our presence is advancing our portfolio. At the beginning of this year, we received regulatory approval for a new treatment option for hereditary angioedema (HAE), in Australia, the UK, and Europe, which was only recently approved by the European Medicines Agency… CSL has been committed to the HAE community for over 45 years, and this new therapy is a significant step forward in improving patient care.

EF: What strategies do you use to develop local skill sets and equip your team to manage new scientific and technological advancements?

CW: I think it is not just about introducing new treatments to the market—it is also about adapting as a company and developing the right skills to support these innovations. We need to strike a balance between experienced employees, whose knowledge and achievements are invaluable, and new colleagues who bring fresh perspectives from other parts of the industry, or even different industries. This mix helps us evolve not just our business model but also the way we approach innovation. Take for example the first gene therapy for hemophilia B approved in the EU, representing a groundbreaking scientific advancement. Beyond the science, it also introduces new challenges in terms of making such a treatment accessible and sustainable within public healthcare systems. Unlike traditional therapies that require lifelong treatment, this is a one-time therapy with the potential to significantly improve a patient's quality of life. However, the financial model for such treatments is different—it presents an upfront cost rather than ongoing payments, which can put pressure on healthcare budgets.

Addressing these challenges requires a team that is innovative, adaptable, and willing to tackle new problems head-on.

EF: Can you provide an overview of Germany's strategic importance to CSL Behring and your commitment to the country?

CW: Germany is one of our most important markets, not just for business growth but also for research and manufacturing. The country has a strong ecosystem for the plasma industry, and we want to ensure it remains attractive in the future. That is one of the key challenges my colleagues and I are working on. Currently, CSL employs over 4,000 people in Germany, with a major presence in manufacturing, commercial operations, and research. Marburg, in particular, plays a crucial role, in producing therapies for patients in more than 100 countries. The site is closely linked to our commercial footprint in the Frankfurt area and is part of our effort to build a strong innovation ecosystem for life sciences. Marburg has deep roots in the biotech and healthcare sectors, with strong partnerships between CSL Behring, local startups, policymakers, and universities. To reinforce our commitment, CSL has invested more than €600 million in the Marburg site in recent years, including a state-of-the-art base fractionation and one of its largest R&D centers in the world, located in the heart of Germany. Additionally, we operate 17 plasma collection centers across the country, ensuring we maintain a strong and independent supply chain, reducing reliance on plasma collected in the U.S., especially given global uncertainties like elections and policy changes.

The pandemic highlighted the importance of a stable plasma supply. During that time, we faced significant shortages of plasma-based therapies, which are essential for patients with chronic immune deficiencies. To avoid future shortages, we need a business environment that supports both manufacturing and commercialization. Increasing production costs, energy prices, and inflation present significant challenges, especially in the plasma industry, where manufacturing is more complex and expensive, based on longer production and planning cycles compared to producing traditional pills. Since plasma collection costs are high and cannot be easily scaled, we need policymakers to recognize the unique challenges of plasma-based therapies.

To support the industry, we must raise public awareness about the importance of plasma. The government plays a key role in educating the public and ensuring policies protect sustainable patient access to plasma therapies. One major issue is the practice of mandatory discounts on plasma-based products. With global demand for immunoglobulins exceeding supply, imposing price controls in Germany could drive these critical products to other markets, putting German patients at risk. Additionally, policies like the automatic substitution of plasma therapies, similar to what happens with generic drugs, are problematic because there are only a few manufacturers, making such substitutions impractical and potentially harmful.

EF: Are you working on any initiatives to raise awareness about diseases like hemophilia and plasma-related therapies for stakeholders, patients, and their families?

CW: We are deeply committed not only to plasma-based therapies but also to advancing treatments in the key therapeutic areas we focus on. Our goal is to make a real difference in the lives of patients and their families. To achieve this, we focus on what we do best—research, development, manufacturing, and ensuring patients can access our products. Beyond that, we actively support patient advocacy groups and scientific communities to raise awareness, educate healthcare professionals, and foster scientific discussions. We see ourselves as part of a larger healthcare system and work closely with various stakeholders to drive progress which clearly include payers and policy makers as well.

One major breakthrough in healthcare is gene therapy, which has the potential to transform medicine by treating or even curing diseases previously considered untreatable. This is not just about our asset, but about a broader revolution in treatment. However, while gene therapy offers incredible opportunities, it also presents major challenges in terms of funding and infrastructure. Regulators, such as the U.S. FDA and the European EMA, anticipate around 20 new gene therapy approvals per year in the coming years. This means healthcare systems, especially in Western countries, must prepare for both the benefits and financial challenges that come with these innovations.

At the start of 2023, CSL Behring achieved a significant milestone when the first gene therapy for hemophilia B, received approval from both the FDA and EMA. This treatment can significantly reduce bleeding episodes with just a single infusion. However, bringing such a groundbreaking therapy to patients requires more than just approval—it also requires new approaches to reimbursement and pricing. To ensure patients can access gene therapies, we need to rethink how these treatments are funded.

In Germany, we are currently negotiating pricing with the national health insurance (GKV-SV). Our proposal is a success-based annual payment model, which ensures predictable costs and aligns with the price of existing long-term treatments. Under this model, reimbursement would be spread out over several years, only continuing if the treatment proves successful. This approach could make gene therapy more sustainable for healthcare systems while ensuring faster access for patients. We are excited about this initiative and remain committed to working with stakeholders to find sustainable funding solutions for innovative therapies. Our hope is to successfully conclude these negotiations in the first quarter of this year and continue driving medical innovation forward.

Andreas Burkhardt

Teva Pharmaceuticals
SVP General Manager, Germany | Chair, ProGenerika, Germany

EF: What are the priorities on your agenda right now, and what can we expect from Teva in 2025?

AB: The generic industry in Germany is grappling with significant challenges. These stem from strict regulatory mechanisms aimed at driving down prices, which are enforced by authorities. This has resulted in supply shortages and made it increasingly difficult to deliver a broad portfolio of generics to patients in Germany. Addressing this issue remains a key focus for us.

For the first time, the Minister of Health acknowledged that excessive pressure and minimal margins are the root causes of the current situation. However, the impact of the new legislation has been minimal, covering just 1% of the portfolio.

Despite these limitations, some progress was made, particularly with children's medication. The Minister analyzed areas of supply shortages and took appropriate measures, such as halting tenders and easing price pressures to stabilize supply. While these actions are commendable, they must be expanded to include more products to create a sustainable system. The inability to adjust generic pricing, especially in the face of inflation over the past 3 years, has exacerbated the issue. Rising costs have placed additional strain on an already tight system.

The legislation has also introduced new requirements, such as extending product storage to six months. This approach, while well-intentioned, is impractical, especially for products already in short supply across Europe. It forces production to prioritize warehousing rather than fulfilling market demands.

Internally, our focus will also include profitable growth in order to support our pivot to growth strategy and prepare for upcoming product launches, which represent a significant opportunity, but they also require careful preparation.

Another pressing issue is the EU's Green Deal and its implications for the pharmaceutical industry. For instance, the Urban Wastewater Treatment Directive (UWWTD) mandates building advanced purification systems across Europe. The pharmaceutical and cosmetic industries are expected to fund the associated costs, which could reach double-digit billions. With no ability to raise prices, this poses a severe challenge. The rationale behind targeting these industries remains unclear, and such measures risk undermining European healthcare systems. Additionally, we face uncertainties surrounding the implementation of this legislation, as individual countries are now tasked with determining how to enforce it.

Numerous legislative challenges are impacting the pharmaceutical industry, one of which involves F-gas, a critical component used in pressurized inhalers. These inhalers rely on F-gas, and if their use is restricted under new environmental regulations, the industry will face significant hurdles. First, manufacturers would need to redesign these inhalers, which is no small task. Second, this would increase production costs in an environment where margins are already extremely low.

For example, products like salbutamol for asthma patients are already unprofitable under current conditions. With the introduction of this legislation, continuing to produce such items would be financially unviable, potentially leading to supply shortages for patients who rely on them. This is a critical issue, as it does not merely impact businesses but directly threatens patient access to essential medicines.

We are among the few companies striving to maintain an equal balance between innovative and generic businesses within a single organization. This hybrid approach is unique and presents a compelling opportunity for us. On one hand, we can achieve growth through the introduction of new products and the implementation of a forward-looking strategy. On the other hand, we can focus on improving the efficiency of our generics footprint and optimizing operations to make it more sustainable and effective.

EF: Could you elaborate further on the generics landscape in Germany from Pro Generika's perspective? From Teva's standpoint, how crucial is it for the company to be actively involved in shaping the future of this landscape?

AB: At Teva, we are one of the largest, if not the largest, healthcare medication providers in Germany. When you combine our generics and OTC offerings, we are undeniably the volume leader. This gives us a substantial presence in the market, and with that comes the responsibility to advocate for the system and fight for our patients.

Germany has one of the highest generic conversion rates, with 80% of medications being generics. However, we are heading in a problematic direction. The country increasingly depends on Indian and Chinese suppliers. While there is nothing inherently wrong with these suppliers, an overreliance creates vulnerabilities. A balanced approach is necessary, but the current system in Germany not only fails to encourage balance but actively disadvantages local or regional production due to stringent regulations and bureaucracy. This gives an advantage to countries with fewer constraints, where production costs are lower.

EF: Could you provide an overview of why Germany holds strategic significance for Teva as a global group and where you see potential for continued investment in the market?

AB: Germany is strategically significant for Teva due to several factors. First, in terms of pure numbers, Germany is the fourth-largest pharmaceutical market globally and the second-largest market for Teva after the U.S., albeit with a notable gap.

Historically, Germany's importance grew significantly with Teva's acquisition of Ratiopharm. Before this acquisition, Teva's presence in the European generics market was limited and fragmented. The acquisition elevated Teva's position in Germany from 15th or 20th place to 1st or 2nd, underscoring the strategic value of the German market.

Additionally, Teva has established complex production capabilities in Germany, particularly in Ulm, which is home to facilities producing solids, supplements, creams, and ointments. This site also houses the largest sterile nasal spray manufacturing unit within the Teva network, showcasing the advanced technologies and expertise concentrated here. These capabilities are unique and vital to Teva's global operations.

One notable example is the decision to establish a biopharmaceutical production site in Germany. I was part of the team promoting the German site during an internal competition led by an external company.

Despite other countries offering significant tax benefits, the decision clearly favored Germany. The rationale included the availability of a highly educated workforce and the advantage of being part of a biopharma cluster stretching from Germany to Milan. Within a four-hour radius, the region is home to numerous biopharmaceutical companies, institutions, and universities specializing in this field. These factors were decisive, given the complexity of biopharmaceutical production and the need for expertise to manage it effectively. The strong pool of talent and resources in Germany ultimately made it the ideal choice.

EF: How is Teva's "Pivot to Growth" strategy being translated into the German market, and are there any upcoming innovations you're particularly excited about that will contribute to the growth of Teva in Germany?

AB: We are preparing to launch products that have already been released in the U.S., such as one for tardive dyskinesia. Additionally, we are working towards the launch of a product for a long-acting version for schizophrenia. The preparations are well underway. We are also supporting studies on our Anti-TL1A product, for which we recently released promising Phase 2 results.

In this regard, you may be familiar with Germany's AMNOG system, which requires companies to prove their drug offers added value compared to the current standard of care. If successful, this allows for price negotiations and the potential for a higher price than the standard. The process is clearly defined, detailing the data and structure required to meet these criteria.

"We have a solid footprint in Germany, with a broad portfolio. Our goal is to offer innovative products that address unmet needs and contribute significantly to the healthcare budget by providing generics."

Urs Voegeli

J&J Innovative Medicine
Managing Director, Germany

EF: What mission did you set for yourself in Germany, and what do you want to achieve there?

UV: I'm incredibly happy and grateful to be back in Germany after six years. Living and working for Johnson & Johnson in different countries, as I did, gives you a fresh perspective and helps you see your work globally. We are 100% focused on innovation. Our goal is to develop groundbreaking medicines and make them available to the right patients as quickly as possible, both now and in the future. We likely have the strongest pipeline in the industry, with an investment of around $60 billion in the past two years alone. That speaks to our commitment to addressing unmet medical needs.

On top of that, my aim is to engage deeply with thought leaders from all areas of the German healthcare system, including patient organizations, physicians, scientists, policymakers, and industry associations, to understand both the medical needs and the challenges in this market and figure out how we can overcome them to help patients even more. Finally, there's a bigger question we need to address: how can we make Germany's healthcare system more future-proof? We need to ensure both patient access to medical innovation and a stronger position for Germany as one of the leading countries in medical research. There's incredible talent here, but Germany has lost its global edge. Once again, we want to help change that and make it a top destination for pharmaceutical innovation.

EF: How do you assess the current landscape in Germany? How can we get back to futureproofing and making Germany the pharmacy of the world, and what are the hurdles in that respect?

UV: Having an international career and working in different markets puts things into perspective. Take Australia, where I worked for the past two years. The industry there launched a campaign called The World's Biggest Waiting Room because patients often face long delays. On average, they wait more than a year and a half longer than patients in Germany for drug reimbursement, if they get reimbursed at all. The overall availability of innovative medicines is also much lower compared to Germany. So, while Germany is a large market, it still stands out for its value-based and relatively fast reimbursement system. That's a definite positive. However, medical progress has led to an erosion of the value-based core of the German AMNOG. We need to modernize the system to ensure that patients can rely on having early access to innovations when they are in need.

The National Pharma Strategy was one of the most significant developments during my time away. It was a clear signal from the previous government, acknowledging the pharmaceutical industry as a critical sector for Germany and laying out plans to boost research, manufacturing, and access to innovation.

There have been early steps in the right direction, such as the Medical Research Act, which sets priorities and KPIs for medical research in Germany. It's a good start in closing the gap with other countries by improving speed and cutting bureaucracy. But that's not enough. The real goal shouldn't just be to catch up. It should be to position Germany as one of the leading countries in medical research and innovation. With its wealth of talent and resources, there's no reason it can't reclaim that status.

EF: What is the strategic significance of Germany to J&J as a global group? How does the value that Germany brings as a country go beyond just being a big market?

UV: First is early innovation. Germany has some incredible startup companies we're already collaborating with, and we want to build on that further. The country also has top-tier medical universities and hospitals, making it a strong environment for large clinical trials.

Another crucial factor is Germany's reimbursement system. To ensure reliable early access to innovative medicines and therapies even in the future, it is critical to modernize this system in a value-based way. Frequent policy changes create uncertainty that doesn't align with our long research and investment cycles that span up to 15 years. A stable policy framework and reliable innovation-friendly framework conditions are key to fostering innovation.

EF: With the perspective of having worked in different markets, how do we assess Germany when it comes to making sure patients get these groundbreaking innovative treatments, and how can we make sure they get access quicker?

> "Our pipeline is one of the strongest in the industry, and we are deeply committed to addressing tomorrow's unmet medical needs, from cell and gene therapy to interventional oncology and drug-combination devices."

For Germany to remain an innovation-friendly market when these breakthroughs reach reality, several things must happen. First, we need predictability, clear and stable guidelines on evidence requirements, comparator treatments, and clinical trials that are fit for purpose. This is where we strongly advocate for reform. Germany's current pricing and innovation assessment law, AMNOG, is 14 years old, but medical advancements have grown exponentially. While AMNOG's core principle of value-based healthcare remains critical, it needs updating to reflect modern medical innovation. This means two things: first, adapting to new technologies like cell and gene therapy to ensure proper measurement of their value, and second, redefining clinical endpoints.

Our position is clear: AMNOG reform should be driven by science and evidence. The new government must take action to sustain Germany's role as a market where patients can access groundbreaking medical innovations quickly, reliably, and predictably when they are in need.

EF: Do you have anything upcoming in the pipeline that sparks your interest or something you think will impact the patients within your market?

UV: I am particularly excited about a groundbreaking advancement from J&J: an interventional oncology drug-device combination that has shown promising early trial results. I can't talk with an oncologist today without them asking me about this therapy. They are genuinely happy because they see how much this could change patients' lives—not just by improving treatment effectiveness but also by making a real difference in their quality of life. What excites me is how combining a drug with a device creates a more precise, targeted approach. This means better patient outcomes, with fewer side effects and less burden, which is important in cancer care. It's a great example of how innovation can tackle unmet needs meaningfully, and I feel incredibly proud to be part of it.

EF: What would you like to share as a final message or mission for the future? What do you hope for the coming years now that you are back in Germany?

UV: Looking at Germany on a broader scale, it's time to be bolder than ever, to think big and stay connected. Healthcare policy is also economic policy, and we need to connect the dots, plan for the long term, and act with a strong sense of urgency for what needs to be done today. I'm fully committed to this. By working with industry players and key stakeholders, I am confident we can achieve the best patient outcomes while strengthening this country's medical and scientific industries.

Thomas Weigold

Sandoz & Hexal

Country President Sandoz Germany And Chief Executive Officer, Hexal AG, Germany

EF: As you continue to execute the company's purpose-driven strategy, how does that translate to Germany, and what does this year have in store for you?

TW: Germany is actively involved in nearly every aspect of the healthcare system, and as a company, we're proud to be the leader in this market. Every year, we sell 200 million packs in Germany, and in terms of size, we're comparable to our two main competitors, Ratiopharm and Stada combined. We operate across multiple segments, from biosimilars in the retail sector to OTC products, covering the healthcare system's and patients' essential needs.

> "We're at the forefront of launching new products, and in many cases, Germany is one of the first markets to introduce them. That's part of our purpose: pioneering access for patients."

What excites me most about this market is that we're continuously shifting from exclusive originator products to expanding access through what we do. We've seen this clearly in the biosimilar sector. It's not just about offering a more affordable option that eases the financial burden on healthcare systems. It also allows doctors to transition patients to biosimilars or biologics much earlier, creating a double positive impact on society.

Our goal remains to meet basic market needs while being among the first to introduce more affordable medicines. Looking ahead to 2025, we see many opportunities where this approach can make a real difference. The cost pressures across Europe, particularly in Germany, are growing, and we can ease that burden by providing affordable medicines to a much broader population.

EF: What do we need to do now to ensure financial sustainability for generics in Germany in the years to come?

TW: This is one of the biggest challenges we're currently dealing with. If you look at the German healthcare system, it's clear that we need to do a better job of educating people about the reality of pharma. Pharma isn't just one thing; it's not just about innovation and breakthroughs. About 20% of the market consists of originator drugs, some groundbreaking, offering exciting new treatment options. Still, they also come with a hefty price tag and serve only a fraction of the population. A strong healthcare system needs innovation. But what often gets overlooked is the remaining 80% of the medicines, generic medicines people rely on daily.

With ongoing shortages in Germany, people finally realize the impact of that neglect. They're wondering why certain medications are suddenly unavailable as if they were always a given that antibiotics or cancer treatments would just be available. But we haven't been taking care of this segment as we should. Now, factor in how quickly Germany's population is aging. If you project five years ahead, the demand for medicines will increase dramatically. Whether politicians like it or not, this issue needs attention. But so far, the response has been to keep squeezing costs. That strategy is hitting its limit.

As an association, we've proposed how to manage at least the most critical medicines, those 200 to 300 products where shortages cannot occur. Our approach is to monitor these medicines throughout their life cycle. There must be an early warning system as they move into a yellow or red zone, meaning supplies are shrinking, and fewer companies are producing them. Right now, the pattern is predictable: you start with 20 suppliers, but over five years, intense cost pressures drive most of them out until only one or two remain. The key question is: when do we step in and reform the system to prevent this from happening? Because once you reach an oligopoly, it's bad for businesses, patients, and the entire healthcare system.

At some point, we have to stop basing everything on price alone. Instead, we should create a system that allows multiple suppliers to share the market as we do with biosimilars, which has worked well. Prices still come down, but we also maintain a reliable supply.

The challenge, of course, is getting our voices heard. We're working on this individually, through conversations, and collectively as an association, bringing these proposals to the table. The segment of the market that's often ignored, the one providing 80% of medications at a fraction of the cost of big pharma, is crucial. To put it in perspective, let's look at Europe as a whole. Generics typically comprise about 70% of medications and 30% of healthcare budgets. But it's even more skewed in Germany: generics represent 80% of drugs, yet they only receive 7% of the budget. This imbalance explains why Germany faces such a unique problem after 15 years of this model. It's also why more and more companies are exiting the market. Having worked in Poland, Switzerland, and Sweden, I know that the balance between financing innovators and generics is fundamentally different in those countries. We need to address this before it's too late.

EF: How do you leverage Germany as a manufacturing and exportation powerhouse?

TW: We've been deeply committed to producing locally in Germany for decades. This commitment began under Sandoz and continued with the companies we acquired in 2005, like Hexal and 1A. It makes sense to have factories close to your consumers, and that's exactly what we've done. Salutas, our factory in Barleben, is celebrating its 30th anniversary this year. It's one of the largest factories globally, producing an incredible 10 billion tablets annually. Half of that output stays in Germany, while the other half is exported to around 100 countries. It's a facility we're incredibly proud of, and we're grateful for the support we receive from the local government.

Our site in Rudolstadt focuses on inhalers and asthma products. In Holzkirchen, we have our German headquarters and a factory specializing in patch production, a complex technology not many companies invest in. We expanded the site two years ago by investing in a new biosimilar development center. Altogether, this gives us the largest consolidated footprint of any Sandoz country. It demonstrates our commitment to manufacturing in Germany and research, development, and serving the local market.

Out of the 10 billion tablets we manufacture, a significant portion falls into key categories like cardiovascular treatments, hypertension, diabetes, and pain relief. That makes up a major part of our portfolio. At the same time, we participate in tenders, leveraging our scale in Germany and across the entire company. This allows us to take advantage of economies of scale, which is crucial when you must be efficient and price-competitive. In this segment alone, we have around 2,800 products.

Then there's OTC, where we also have a strong presence. Biosimilars are a relatively newer player in our portfolio but have grown steadily since we entered the space more than 15 years ago. Germany was one of the first countries to introduce biosimilars. Developing biosimilars requires specialized expertise, but we have the knowledge and capability to develop, manufacture, and market these products in-house, which gives us a huge advantage.

The biosimilar landscape is set to expand significantly over the next 10 years; around 100 biologics will go off-patent. In Germany, we've taken a smart, strategic approach rather than rushing into the market. We already have 10 biosimilars on the market, with plans to launch four more this year alone.

EF: Do you have a final message you would like to share, something you wish to add about 2025 that excites you, or any reflections to wrap up the interview?

TW: We are in a situation where, as a company, we have a big role to play in serving society with affordable medicines. But at the same time, we also need to speak up when we see things heading in the wrong direction. High bureaucracy, over-regulation, and high price pressure can become an unfavourable mix. Germany and Europe have an ongoing political debate about supporting local production better. But we need to go beyond just talking about it, we need real incentives. One example is antibiotics. We finally got a law that includes a dedicated slot in tenders for European production. That's a step in the right direction. One of the largest penicillin production sites isn't in Asia or Latin America but in Austria. So, we know it's possible. The next step is scaling that approach to other areas. It's about rebalancing our current over-reliance on global supply chains, which is no longer sustainable. Every country has the right to encourage local production, and we should actively invite companies to build factories here in Germany.

Manfred Heinzer

Amgen
Vice President And General Manager Germany

EF: How do you assess the current environment in Germany following the key legislative changes, and how has Amgen's work been affected by the recent legislative changes?

MH: Germany has traditionally profited from the cutting-edge pharmaceutical sector; thus, this sector is significant to our country's economy. However, Germany lost its competitiveness over time compared to the USA and Asia Pacific. Due to budgetary constraints, the health ministry at the time introduced the Statutory Health Insurance Stabilization Act, which had three main components: first, they introduced additional AMNOG "guardrails"; second, they increased the mandatory rebates by 5% for 2023; and third, they introduced a combination rebate of an additional 20% for all medications that will be applied in combination therapies. This fundamentally undermined an innovation-friendly environment. While it did save some money to some extent, in the short term, it sent devastating signals and made innovation much more difficult, creating a hostile and constrictive environment for pharmaceutical companies in Germany.

Since we achieved a better understanding of the interlinked consequences of health, innovation, and economics policy, the federal government of Germany finally started to recognize that the innovative pharmaceutical and biotech sector is one of the few strategically significant industry pillars for the first time. Through their Pharma Strategy, the federal government highlighted eight distinct activities that will not only improve the state of our industry but also increase our competitiveness in terms of clinical research and prevention. These activities include, but are not limited to, enhancing clinical research, reducing bureaucracy, and utilizing digitalization. Overall, despite the difficulty we faced in 2023, the government realized they needed to make changes because they saw us finally not only as a cost factor in the health sector. They saw us as an important contributor to and access to innovation in conjunction with academia and clinical trials, as well as the economic contribution our industries bring to the country as an industry.

EF: Could you briefly describe Amgen's presence in Germany and the country's strategic importance to Amgen as a global organization?

MH: Germany is a country in which innovative pharmaceutical treatment options are launched first in general. Therefore, this has an elevated strategic value in the pharma sector, as well as for us as Amgen with headquarters in the United States. This essentially ensures instant access to innovation and innovative treatments for patients in Germany. Founded in 1980, Amgen is considered the world's largest independent biotech company. First and foremost, Amgen's primary goal is to thrive on a global scale by leveraging biology and technology to truly address some of the most difficult diseases around the world. In Germany, we have clustered our portfolio and medical offerings into four big therapeutic areas: oncology and hematology, cardiology, bone and inflammation, and rare diseases.

These pillars are focused on discovering medications that would ultimately improve humanity by enabling patients to live longer, better, and more fulfilling lives.

As we dug deeper into oncology and hematology, we pioneered cancer treatments that specifically target one of the most difficult diseases in the tumor area. Among these is the bispecific T-cell engager technology platform called BiTE. This research site is also based here in Germany, south of Munich. Due to its longstanding research focus on BiTE technology, Amgen Research Munich is one of our major research centers.

Another crucial therapeutic area is cardiology, which is among the most prevalent diseases in our society. For instance, cardiovascular diseases have been responsible for around 350,000 fatalities in Germany last year. By addressing the main risk factors for heart attacks, such as LDL cholesterol regulated by PCSK-9, the likelihood of heart attacks, strokes, and other cardiovascular events can be significantly reduced. According to the WHO, osteoporosis is another significant area where there is still a high level of undertreatment leading to fractures. Approximately 6,000,000 German patients, mostly women, remain untreated, representing a sizable fraction of the population. Our medicine significantly reduces the risk of fractures with a bi-annual therapy. Another key therapeutic area is rheumatoid arthritis and Crohn's disease, which affect millions of people in Germany.

The recent acquisition of Horizon Therapeutics allowed Amgen to access the highly unserved new field of rare diseases, which complements our existing portfolio very well.

As one of the pioneers in biotechnology, Amgen is one of the key experts in efficiently manufacturing biologics. Hence, biosimilars complement our portfolio within the identified four therapeutic areas. Amgen, therefore, offers further options for more affordable options each time a respective patent of a biological medicine expires.

EF: Do you, as Amgen, see a clear road ahead for bringing also rare disease treatments to market in Germany?

MH: Yes, we do. However, based on the very low patient numbers, it is often difficult or even impossible to find the appropriate comparator treatment in the clinical development programs. Hence, in collaboration with our pharma association vfa, we are attempting to modernize the AMNOG methodology, which has demonstrated value for more than a decade. Particularly for gene and cell therapy, the current AMNOG philosophy will have to evolve if patients in Germany will still benefit from early access to these innovations.

EF: The topics of AI and technology are hotly debated. How can you concentrate on practical, helpful uses of technology to improve your workflow and ultimately help the patient?

MH: Our organization has always relied heavily on innovation, which will support our mission 'To Serve Patients.' Internally, we consider it to be one of those pivotal times when our industry can benefit from combining both technological and biological innovation. We are currently focusing on merging these two technologies. We have also had the good fortune to collaborate for years with companies that specialize in artificial intelligence, such as OpenAI and Microsoft. As a result, we aim to use this technology to accelerate innovation throughout our entire value chain.

As a company, we completely embrace technology, and we have been making significant investments in data science, artificial intelligence, and other technologies for years. Our goal is to develop next-generation medications with the greatest possible impact. For instance, we discovered that AI will fundamentally change the way we conduct business along the whole value chain. We have already reached a point in the lab where we can significantly shorten the time for research and clinical development.

For this reason, Amgen has also developed a supercomputer named 'Freyja' in collaboration with NVIDIA. It's located at Amgen's deCODE genetics headquarters in Reykjavik, Iceland. It will assist our organization in analyzing the vast amount of data.

EF: As Amgen approaches its 45th anniversary, what message would you like to convey to your staff as you reflect on your achievements in Germany and approach this milestone?

> **“Amgen is an amazing company that has demonstrated over the years and decades that we truly place innovation at the forefront with discovering first- or best-in-class medicines in therapeutic areas of high unmet medical need.”**

Let’s together embrace our unique moment to maximize innovation by applying artificial intelligence across all of our key business processes to accelerate processes or achieve results more efficiently. At this point, we are on a great path; the groundwork is solid, and we anticipate a bright future.

Rüdiger Schulze

Ultragenyx
Vice President And General Manager, DACH

EF: How have things evolved over the past two years since we last met, and what are the current priorities on your agenda?

RS: Ultragenyx has successfully created a drug that addresses an important unmet need in homozygous familial hypercholesterolemia. At the same time, we're moving forward with our research pipeline, as Ultragenyx remains focused on innovation. We are conducting clinical trials for six different rare diseases, most with participating German investigators. For example, the clinical study for long-chain fatty acid oxidation disorders is now fully enrolled, as is the study on osteogenesis imperfecta. We're also progressing programs for glycogen storage disease type 1A (GSD1a), ornithine transcarbamylase deficiency, Wilson's disease, and gene therapy for mucopolysaccharidosis type IIIA, a very severe lysosomal storage disease for which there is no specific treatment, yet. Another promising development is the antisense oligonucleotide for treating Angelman syndrome that has started to enroll patients for a Phase 3 study, with several German sites involved.

EF: How do you assess the national pharma strategy from a rare disease company's perspective?

RS: It's a step in the right direction. The German government has begun to recognize that the pharmaceutical industry can create high value with minimal energy use. Due to Germany's intentionally high energy costs, Germany has lost competitiveness in several other sectors. It is clear that improvements are needed, especially after the major setbacks following the act on stabilizing statutory health insurance financing (GKVFinStG). This has unnecessarily made access to much-needed innovation more challenging.

EF: How can we address late diagnosis and the clear shortfall in younger people and children, and how can policy and education be enhanced to push earlier and more accurate diagnostics, especially regarding rare diseases?

RS: We could learn from countries that diagnose patients faster, allowing earlier treatment, better quality of life, and in many cases longer life expectancy. The gold standard for early diagnosis is newborn screening. In Germany, the process to include more diseases in newborn screening is unfortunately very slow and has not kept up with recent progress in science. Take lysosomal storage disorders, for example, which are currently not part of general newborn screening. With current therapeutic interventions, deterioration of neurological function can be prevented in many patients. Therefore, it is crucial to detect these patients at a very young age. With generalized genetic newborn screening, finding these patients before the emergence of irreversible symptoms seems much more likely. Despite the advances in big data analysis and artificial intelligence, the time to establish the right diagnosis is still much too long - many patients still go through a revolving door of specialists without getting real answers, particularly in diseases with apparently unspecific symptoms. Fortunately, Germany has a strong infrastructure with rare disease centers established over a decade ago. However, the referral patterns to these centers could be more effective. A unified registry across multiple rare diseases, could be a major improvement by helping generate real-world evidence, especially in areas where natural history data is limited.

EF: What are the main priorities for rare diseases in the DACH region overall, and what do we need to align on to move forward innovation?

RS: Despite efforts from the scientific community, patient advocacy groups and industry, many rare diseases remain underdiagnosed and undertreated. Because of the complexity of our healthcare systems, bringing stakeholders together can be eye-opening and mutually beneficial. Over the past year, I've spoken with many individual payers and health insurers to better understand their challenges. Their predicament is that the government makes promises that cost sick funds extra money, leaving statutory health insurance with no other choice than to raise extra premiums, which damages their competitive position and their reputation. It would benefit patients and payers if we address inefficiencies in the healthcare system to liberate resources that patients with rare diseases need. Market access remains a major challenge, and I wonder how this will change next year when the Joint Clinical Assessment on a European level enters into effect for ATMPs. It might improve access if real-world evidence is recognized more often than currently in Germany. The JCA may also accelerate access in countries that do currently not maintain an HTA, which would be welcome, but the JCA will not replace current HTA processes in Germany and other countries. Instead, it adds another bureaucratic layer and extra costs. We need to learn from experience with this new regulation and jointly flag anything that does not serve the interests of patients.

Since the inception of AMNOG, around 50 drugs have exited the German market due to unsustainable pricing. Beyond those that exited, additional drugs were never launched at all, and the government has recognized that the strict pricing guardrails imposed by the Act on the Stabilization of Statutory Health Insurances Financing (GKVFinStG) made things worse by limiting access to innovative treatments. This could put Germany behind other countries in terms of therapeutic standards.

EF: What do you look forward to seeing in 2025 when celebrating the past 15 years since Ultragenyx's establishment?

> "Ultragenyx is a phenomenal success story, we have developed meaningful innovations for patients in a very short time and we're only just getting started."

I am a strong supporter of emerging markets, so I hope that Ultragenyx will be able to expand into more geographies. I also hope that the positive shift in biotech financing continues, with more investors showing interest in our industry. Biotech relies on venture capital, as the majority of innovation in rare diseases comes from small companies. This is an area where Europe is lagging far behind the USA. Europe has excellent researchers, but we need to be more effective in financing start-ups. In Germany, the new Medical Research Act, which is about to enter into effect, introduces confidential pricing options for companies under certain conditions. Though it includes an additional 9% slashed off the negotiated price, having this option is a big step forward

Andrea Passalacqua

Alexion
Vice President And General Manager Germany

EF: What are your top priorities now, and what can we expect from you in 2025?

AP: We have been leaders in rare diseases for 30 years and are pioneers in the field of complement biology. The complement system is a key part of the immune system, and this foundation has shaped our work. Globally, we have around 5,200 employees. In Germany, we have a strong presence with over 200 employees. Our focus is exclusively on rare diseases, and we provide treatments for seven of them. In Germany, we have six approved therapies and are actively involved in over 20 clinical trials across 120 centers.

> “We aim to maintain and strengthen our leadership in rare diseases by 2030. Our goal is to bring at least five new drugs to market by then.”

Currently, Alexion operates in 70 countries, separate from AstraZeneca's footprint, and we plan to expand to more than 100 countries by 2030. That gives a broad overview of Alexion's global vision.

Regarding our priorities for Germany, it is essential to have a clear and focused set of priorities rather than too many. With a team of just 200 people, maintaining focus is key. Our first priority is aimed at staying true to our mission and ensuring that everything we do aligns with Alexion's purpose.

The second priority is preparing for multiple parallel launches over the next three to four years. Our pipeline includes several products across various indications, all focused exclusively on rare diseases. This will be a demanding period, and we must be ready.

The third priority is improving diagnostics. As you may know, diagnosing rare diseases remains a major challenge in Germany and globally. It can take up to five years for a patient to receive a diagnosis, and even when they do, more than 90% of rare diseases currently have no available treatment. Addressing this issue will be an ongoing priority for us.

The fourth priority is influencing healthcare policy, particularly concerning rare and orphan diseases. Rare diseases come with unique challenges that must be reflected in policy decisions.

EF: What is Alexion doing to enhance diagnostics and the patient journey for those with rare diseases?

AP: The majority of our work in the rare disease space is focused on supporting diagnosis. It is remarkable that, even in Germany, a country with one of the highest diagnostic rates, patients still face an average of nearly five years before receiving a diagnosis. While Germany is ahead of many European and non-European countries in this regard, there is still room for improvement. In countries with fewer resources and less access, patients often go undiagnosed for even longer, and awareness of these diseases is significantly lower.

Improving diagnostic rates accounts for about 80% of our efforts. A major part of this involves education - raising awareness that certain rare diseases exist, how they can be diagnosed, and what testing methods are available, whether genetic or biology-based. We also contribute to developing diagnostic tools, methodologies, and algorithms, including integrating artificial intelligence to analyze data more effectively.

Beyond education and tools, we support the medical community in establishing Centers of Excellence—specialized institutions, often university-based, that focus on specific rare diseases such as aHUS, PNH, or gMG. These centers help advance expertise and improve patient outcomes.

Since diagnosing rare diseases is inherently complex, it requires coordinated efforts across industries, scientific experts, and policymakers.

In summary, our approach covers multiple areas: education, diagnostic tools (including AI-driven solutions), Centers of Excellence, and healthcare policy shaping. These elements work together to create a more effective and accessible diagnostic landscape for rare diseases.

EF: How do you evaluate rare disease policy in Germany compared to other markets, and what collaborative efforts are you making to help shape it?

AP: Germany has a strong healthcare system, and its rare disease framework is generally positive.

One key factor is that once a medicine receives EMA approval, it becomes immediately available to patients, with only minimal administrative steps required. This makes Germany one of the top countries in Europe and globally for access to medicines.

Our goal is to maintain these favorable conditions while identifying areas for improvement. Right now, there is ongoing discussion around a potential AMNOG reform, with various perspectives on how it should evolve. We prioritize ensuring that any changes continue supporting facilitated access to rare disease treatments rather than making the process more complex. We want to enhance the system, not make it more restrictive, so patients can continue benefiting from innovative therapies.

EF: How do you view the potential of AI in the field of rare diseases, and what are the challenges to its implementation?

AP: I can see the potential for AI in rare diseases. For example, AI can help with predictive algorithms, where you combine various variables to assess potential diagnoses. This is particularly challenging in rare diseases due to limited data and inconsistent information. However, AI algorithms have the potential to improve over time by self-adjusting and refining their predictions. This could make a substantial difference in diagnostics, even with smaller patient populations.

AI can also play a major role in research and development. It can help streamline the R&D process by processing vast amounts of data more efficiently, potentially benefiting rare diseases and other areas.

Another application is in medical education. AI can assist in processing and summarizing complex medical or genetic information. This could make it easier to educate physicians, healthcare professionals, and patient organizations about rare diseases, ultimately improving knowledge sharing and collaboration.

Additionally, we recently partnered with an American company, Envision, to develop an AI algorithm for analyzing echocardiograms. This collaboration aims to accelerate the detection of amyloidosis with cardiac involvement, enabling earlier and faster diagnoses. This is just one example, and there are many other ways AI could revolutionize the field.

Josip Meštrović

Zentiva

General Manager Germany And Switzerland, Zentiva

EF: How has the company evolved since becoming independent from Sanofi?

JM: From 2017 to 2018, Sanofi shifted focus and stepped away from the generics business. It was sold to Advent International, one of the largest and most experienced global private equity investors. In Germany, this was a huge step toward becoming an independent business. We were starting from scratch, building everything from the ground up, hiring people, securing office space, and structuring the business. Our team grew continuously, and together, we worked to establish what has become one of Germany›s leading generics companies and partners.

The last six to seven years have been incredibly exciting, especially with Advent as a strong strategic partner supporting our journey. There's a huge difference between being an independent company and being part of a big group like Sanofi, and that shift required a new focus. I stepped into the role of General Manager in 2016, taking on the team's leadership. It's been an honor to guide this company through its evolution.

EF: In this year of transition, could you tell us your current priorities and what we can expect from Zentiva?

JM: 2025 will be an important year, especially for the generics industry. With the elections in Germany, we are now seeing a new government taking shape, and major investments are expected in areas like defense, infrastructure, and climate, which is a positive step. From my perspective, ensuring a stable and reliable supply of medicines is as critical as investing in roads, public transport, or schools. Unfortunately, while Germany has neglected infrastructure for decades, the pressure on the pharmaceutical industry, particularly generics, has only increased. We are responsible for ensuring the new federal government understands that key reforms must start now in an aging society like Germany to secure long-term benefits.

Generics account for 80% of all prescribed medicines in Germany but only for 8% of the total pharmaceutical spending by statutory health insurance. Our role as an industry is to ensure widespread access to essential healthcare while financially sustaining the system.

Still, instead of easing rules, we're seeing new burdens, like extended product stockpiling requirements and the Urban Wastewater Treatment Directive (UWWTD). Instead of making the market more attractive, regulations are piling up, and this needs to change.

EF: How will the Directive affect local supply chains and access to affordable medication?

JM: This Directive seriously threatens our viability as a Europe-focused generics company. It creates an unacceptable risk to millions of people by potentially leading to medicine shortages, leaving behind our patients who depend on essential medicines every day. To be clear, we fully support clean water initiatives and the Green Deal. Safe water is crucial for life and medicine production, and we›re not opposing environmental responsibility. However, the way this Directive is being implemented is simply discriminatory. We›re willing to pay our share, but this feels more like an added tax that disproportionately affects the generics industry due to the sheer volume we handle. This is why we are raising concerns about the Directive, not because we oppose environmental responsibility but because the approach must be fair. Regulations should not disproportionately burden the generic industries while overlooking other sectors.

EF: Where do you see additional challenges given the current generics landscape and framework you are operating in?

JM: Uncertainty is one of the biggest challenges. Stability is essential for daily operations and long-term investments in production lines and new sites. With two major European production facilities, Zentiva aims to minimize uncertainty wherever possible. Yet, we are already dealing with enough unpredictability: geopolitical conflicts, fluctuating pricing structures, inflation, and rising energy costs. This is why the European Union must be cautious about protecting pharmaceutical production within Europe. We must ensure that Europe remains self-sufficient in medicine manufacturing, reducing dependencies on China for active pharmaceutical ingredients (APIs). Recent global events have highlighted how reliant Europe has been. Over the past decades, there has been a growing realization across Europe of the need to regain control, and now we are seeing a shift toward strengthening domestic production.

> “With almost 450 million people in the EU, we must ensure a stable and sustainable supply of medicines, including generics, to serve millions of patients. This is not just an industry concern. It's a fundamental responsibility.”

EF: What is the strategic significance of the German market to Zentiva? How does the tendering process need to evolve to reflect a sustainable long-term vision?

JM: Germany remains our biggest market for generics, with a significant portion of production for this market coming from Zentiva's sites in Prague and Bucharest. Unfortunately, the core dynamics of the German generics market haven't shifted much. While there have been some changes, e.g., for antibiotics, the main rule for tenders stays the same: the lowest price still wins.

This system may have functioned for 10-15 years, but times are changing. The pharmaceutical landscape is evolving, and the tendering process must adapt accordingly. A strong and sustainable healthcare system cannot rely only on cost-cutting. We need a new approach prioritizing quality, environmental responsibility, and long-term supply chain stability. My concern lies in how these new regulations are being shaped. Too often, new legislation is introduced without much consideration for or even discussion with the generic pharmaceutical industry. This shows just how complex Germany's regulatory landscape has become. I'm not saying the tender system hasn't led to significant savings in healthcare. It has. But the system needs some breathing room. When we see fewer competitors in the market and an increasing risk of shortages, we should be willing to pause and reassess. Making the market more attractive will bring in new manufacturers and reduce the risk of shortages. We need a little more flexibility.

EF: How are you leveraging common industry spaces to advance the sector, and how important is it for Zentiva to be part of these conversations that shape the industry in the future?

JM: We're not just passive participants; we sit on the boards, engage with decision-makers, and work to ensure they truly understand the complexities of these regulations. Zentiva can't do this alone. We need strong partnerships and a unified voice for the generic industry. In Germany, we've achieved this alignment through the Generics Association (Pro Generika), making it easier for stakeholders to engage with a single, coordinated perspective rather than multiple companies speaking separately. We're not here to oppose every change; we're open-minded, realistic, and focused on securing a strong and reliable healthcare system in Germany. We must consolidate our efforts, collaborate with EU regulators, and ensure our industry's voice is heard at every level. Strong coordination between national and European associations is essential.

Christiane Von Der Eltz

Berlin-Chemie Menarini
General Manager Germany And Executive Board Member, Germany

EF: What drew you to Berlin-Chemie Menarini, and what mission did you establish for yourself when you initially joined?

CE: I was drawn to work for the number one company in the German GP sector, which was very appealing. The opportunity to work for a company with a large Sales Team, especially one with a significant track record of success in Germany, was intriguing. Germany's substantial number of GPs – more than 50,000 – requires a considerable workforce. Another key factor was the business model. Berlin-Chemie engages in numerous collaborations, both on a global scale and locally, working with other companies. Compared to others, this flexibility in the pipeline stood out as an exciting opportunity. Returning to Germany after spending several years abroad added a personal appeal to this role.

EF: What are your current priorities for 2025?

CE: In 2025, our focus is on driving innovation and adopting patient-centric approaches within the German market. Collaboration with key stakeholders remains our top priority. This includes general practitioners, internal medicine doctors, specialists, and pharmacists.

> "We strive to remain the preferred partner in general medicine, both quantitatively and qualitatively, by balancing established and innovative products."

This strategic focus on portfolio development is supported by promising candidates in our pipeline. Our efforts also extend to supporting healthcare professionals through educational initiatives and enhancing patient education. At Berlin-Chemie, one of our core strengths lies in offering a variety of educational events. For both healthcare practitioners and patients, we provide digital tools like our TheraKey app, which acts as a unique resource designed to help individuals manage their chronic conditions effectively.

EF: Considering Berlin-Chemie's significant footprint in the country in manufacturing and research, how does Germany's National Pharma Strategy impact the company?

CE: Two key topics are particularly significant. The first is strengthening Germany as a hub for research, development, and production while providing a reliable framework for pricing negotiations and investments. Maintaining competitiveness on an international scale is crucial for Germany to retain its position as one of the leading pharmaceutical markets globally. In this context, the federal government's development of the pharmaceutical strategy is a positive step aimed at fostering investment. This strategy has brought about new legislation, such as the Medical Research Act, which enhances research conditions and encourages more clinical trials in Germany. It includes measures to incentivize conducting studies domestically and reduces bureaucratic hurdles to make these processes more efficient. Another focus area is the use of big data in medical research. Countries like Denmark are exemplary models in utilizing anonymous, registered data to identify suitable clinical trial centers. At last, Germany is also taking steps in this direction with initiatives such as the electronic patient record (ePA). The Health Data Utilization Act, effective from March 2024, aims to regulate how this data is accessed by stakeholders while ensuring patient privacy and data security. Patients' data will be accessible unless they opt out, striking a balance between utility and safety.

The second key area is addressing cost pressures and ensuring predictability for companies. For pharmaceutical manufacturers in Germany, rising costs for employees and production, such as energy prices, combined with capped budgets for prescription medications, pose significant challenges. The early benefit assessment (AMNOG), for example, needs revision to ensure broader patient access. Current pricing restrictions sometimes hinder the availability of innovative drugs in the German market, which underscores the need for a more balanced approach. These developments represent critical steps forward, but they also highlight the need for ongoing adjustments to maintain Germany's leadership in the pharmaceutical sector.

EF: How are you leveraging AI technology to strategically position the company for the future?

CE: At Berlin-Chemie, we are actively examining the entire value chain to identify areas where AI can enhance speed, efficiency, and even creativity. The opportunities are vast, but to capitalize on them, we must first build knowledge and understanding across the organization. Each department needs to evaluate how AI can drive improvements and contribute to our goals. Managing this transformation also involves addressing the human aspect. Discussions about AI often bring fears—such as concerns over job security or adapting to new roles. While AI offers tremendous possibilities, we need to manage the associated change thoughtfully, engaging our employees from the start, addressing their concerns, and ensuring they are part of the journey. AI's greatest potential lies in its collaboration with people, not in replacing them, and this synergy will drive meaningful progress. I am particularly enthusiastic about secure platforms like the ePA (electronic patient record). When implemented effectively, these tools can significantly benefit healthcare by accelerating diagnoses, enhancing prevention, and improving treatment adherence. They also enable cost savings by reducing redundant tests and help avoid medication-related side effects through better data integration. Another huge area of interest is utilizing the power of AI in drug development. Recently, Menarini announced a second cooperation in this area with Insilico Medicine for a new asset. The potential for AI in healthcare is immense. It can empower patients, support doctors, and drive innovation in research.

EF: What developments in your product portfolio are you particularly excited about?

CE: I would like to highlight an important addition to our portfolio from our recent research pipeline. It is a reserve antibiotic designed for patients who cannot be treated with conventional antibiotics. While it addresses a relatively small patient population, it is a life-saving treatment for those with infections caused by resistant bacteria. This product, launched in November 2024, plays a critical role, especially in the context of the growing challenge of antimicrobial resistance. As this issue continues to emerge as a global health concern, the availability of such treatments becomes increasingly vital.

Johannes Inama

Angelini Pharma
General Manager, Germany

EF: What was the mission you set for yourself when you joined Angelini, and how has it evolved over the past year?

JI: Angelini Germany has an interesting mix of heritage and youth. While Angelini is a company boasting over 100 years of history, its German affiliate is quite young, having been established in the summer of 2020, right in the midst of the COVID-19 pandemic. Initially focused on consumer health, the organization soon expanded by introducing the brain health pillar in early 2021. By the time I joined at the start of 2024, the affiliate was three to four years into its journey and still carried the energy and challenges of a startup.

My mission upon joining was to take this young, dynamic organization and elevate it to the next level—accelerating growth and maturity while building on the foundational hard work laid during those challenging early years. This includes establishing Angelini Pharma in Germany as a trusted and preferred partner for all stakeholders.

Changes were also made in the field operations on both the prescription and consumer health sides, focusing our investments more rigorously to ensure we could succeed in our priority areas. These efforts have created a solid platform to accelerate growth in 2025 and move closer to fulfilling the mission I set out to achieve.

EF: Where do you see the greatest potential for growth, and how significant a role do you believe Germany can play within the broader Angelini Group in the years ahead?

JI: Around five to six years ago, the company's leadership and the family behind Angelini decided to pursue a broader European expansion. A European growth strategy, however, would be incomplete without Germany, given its position as the largest economy and country in Europe. This recognition led to the establishment of the German affiliate in 2020, followed soon after by new affiliates in France and the UK, all part of Angelini's vision for a stronger European presence.

Germany plays a pivotal role in this expansion strategy. It is destined to become a core pillar of Angelini Pharma's international success. While the initial years have been focused on building a foundation, the strategic importance of the German market to Angelini's broader objectives is undeniable. The strong commitment from Angelini Pharma to develop, grow, and accelerate its presence in Germany is both evident and motivating, making this market a critical piece of the company's future.

EF: When introducing your portfolio to a new market, how do you approach its management and prioritize resources effectively?

JI: One of the key aspects that attracted me to Angelini was its broad and diverse portfolio. Over the past 20-plus years, my focus has primarily been on prescription medicine, both in primary and secondary care. What stood out about Angelini is its unique ability to integrate both prescription and consumer health under one umbrella. Here in Germany, we manage both pillars, and I would say they are equally significant to our operations.

On the prescription side, the focus is relatively straightforward. Currently, our portfolio includes one innovative therapy for epilepsy, acquired in 2021 through the purchase of its global ex-US rights. This therapy forms the foundation of Angelini's prescription business in Germany, and our efforts are fully dedicated to its growth.

Our approach focuses on maintaining and growing the strong consumer health pillar, primarily around the key brands. At the same time, we are committed to accelerating the development and growth of our epilepsy therapy, which is still in the early stages of its lifecycle. Together, these priorities ensure a balanced and sustainable strategy for the success of our operations in Germany.

EF: A goal for you over the next two to three years is to take a more active role in shaping the German healthcare landscape. Could you share more about this vision?

JI: Clearly, our focus needs to be on our core competencies—on what we excel at. One of our key areas of expertise is brain health, an area in which Angelini has a long history. We have been involved in providing solutions for conditions like depression, schizophrenia, and, more recently, epilepsy. In Germany, epilepsy is our current primary focus.

However, our engagement in the healthcare environment extends beyond just offering therapies. A good example of this is our Headway initiative, which aims to bring brain health—encompassing both psychological and neurological conditions—into the spotlight as a key societal concern. Our ambition in Germany, as in other countries, is to engage more broadly in the healthcare ecosystem. This involves working closely with healthcare providers, clinicians, researchers, patient groups, policymakers, and payers to develop better solutions for those suffering from brain health conditions.

EF: Could you elaborate on how you are promoting your initiatives around epilepsy to patients and other stakeholders?

JI: Germany has one of the best healthcare systems in the world. Yet, more than 50% of patients with epilepsy remain suboptimally treated. This occurs for several reasons, such as late diagnosis, long delays between diagnosis and starting treatment, or the treatment they receive not being the most effective for their needs. As a result, patients continue to suffer from seizures, many of which could be prevented. Factors like adherence and compliance also play a significant role.

> “Raising awareness, facilitating collaboration, and driving a shift in treatment goals are key to improving the lives of people with epilepsy in Germany and addressing the challenges in the healthcare system.”

Michael Kickuth

Recordati Rare Diseases
General Manager, Recordati Rare Diseases DACH

EF: What are the current priorities on your agenda, and what can we expect in 2025?

MK: About three years ago, we set our agenda, which we call the "Plan on a Page." It outlines our long-term vision for where we want to go, specifically through 2026, which is now fast approaching.

> "Our goal was clear: to become the preferred rare disease partner in Germany."

To achieve this, we have leveraged significant strengths, starting with the breadth of our portfolio. We have one of the broadest portfolios of Orphan drugs in the industry. Our portfolio spans rare diseases, Hematology/Oncology, endocrinology, and metabolism. This also includes multiple pediatric indications, which is crucial, as many rare diseases first present symptoms during childhood.

There are key areas we need to enhance further. The first is what we call "patient detection," ensuring early and accurate diagnosis, which is especially critical in Germagny's decentralized healthcare system. The second is "patient activation," enabling swift action once a diagnosis is made. The rare disease space is indeed becoming increasingly competitive. While successful selling remains a key element, patient activation goes beyond that. It involves encouraging patients to actively seek treatment. One of our biggest challenges is often the "watch-and-wait" approach, which is common in many of the disease areas we focus on. Addressing this mindset is a critical aspect of patient activation.

The third key capability we emphasize is patient adherence. Once a patient begins therapy, a significant effort has already been made to secure the correct diagnosis and initiate treatment. It is vital to ensure these patients continue their treatment to maximize its benefits and prevent drop-offs.

To strengthen these three capability areas—patient detection, activation, and adherence—we have implemented a range of initiatives. Over the past few years, we've made remarkable progress, driving forward innovative projects that are helping us reach the next level.

For example, in Cushing's disease, the time from symptom onset to diagnosis in Germany is twice as long as in other parts of Europe or the U.S. While Germany's healthcare system is robust overall, these gaps in rare disease diagnosis and management are areas we must address to improve outcomes.

EF: Regarding the topic of diagnosis delays. How do we bridge the gap from where we are now to where we need to be?

MK: Firstly, there is a need for a baseline level of disease awareness. While we cannot expect every GP to know about all rare diseases, we should aim to help patients navigate the system more efficiently once certain symptoms emerge. Faster referrals to specialists are a crucial part of this process.

To tackle this, we are adopting a few key approaches. For one, we are working on the policy front, collaborating with policymakers and major medical societies. Together, we are publishing papers that highlight gaps in healthcare delivery specific to rare diseases in Germany. This helps initiate conversations with policymakers. However, we often find that while Germany does have a rare disease agenda, it has not seen as much implementation in recent years compared to countries like France. Our goal is to reinforce these efforts and be part of the solution.

Additionally, we are leveraging technology. For instance, we are integrating our efforts into patient record systems in Germany. This involves embedding algorithms into the software that flags potential rare disease cases, such as alerting physicians when a patient's symptoms might indicate Cushing's disease. These partnerships and tools aim to enable earlier diagnoses and better outcomes for patients.

EF: Could you elaborate on the strategies of patient detection, activation, and adherence and how you are implementing them in Germany?

MK: Let me start with patient detection. We are taking a few approaches here. One involves working on a software solution for physicians in partnership with an external company. The idea is that when certain symptoms appear, the physician is alerted, making them more aware of potential rare diseases. We are collaborating closely with them to develop the right algorithms for early detection.

One thing that sets Recordati apart in the rare disease space is our ability to unlock value both for patients and for the company. On the patient side, it is about ensuring that the therapy finally reaches the people who need it.

What truly sets us apart is that we leave no stone unturned. This level of thoroughness, of "turning every stone," is essential in the rare disease space. It is a key factor in our success. We are fully focused on patients, tirelessly working to bring their therapies to those in need.

EF: How does Recordati Rare Diseases ensure that it attracts and retains top talent, and what are the key skill sets you prioritize in the rare disease sector?

MK: At Recordati, attracting and retaining top talent is a key part of our "plan on a page." To be successful, we need to be an attractive option. While other companies talk about agility and transformation, having been in that space, I can tell you that at Recordati, we are able to genuinely execute those principles. We do not just talk about them; we live them. Our teams are very close to the customers, highly integrated, and empowered to make decisions from the customer's perspective.

This level of agility and empowerment is what makes us such a great employer. It is really rewarding to be part of a small but influential team that is truly making an impact on patients.

Marion Bock

IBSA

General Manager, Germany

EF: Why is Germany a crucial market for IBSA to establish a direct presence, and why is now the right time to make this move?

MB: My original question at the time was why we had not moved to Germany sooner. The answer was that the focus had been on core markets like Switzerland and Italy. You might already know that IBSA Group was founded in 1945, but we will not actually celebrate 80 years next year—instead, it will be 40 years. In 1985, an Italian, Dr. Arturo Licenziati, a visionary and entrepreneur, acquired the company and transformed it into what it is today—a completely different IBSA. Originally a group of biochemists based in Lugano, it evolved into a dynamic business-focused company, expanding rapidly and becoming the largest family-owned private Swiss pharmaceutical company.

About three years ago, the company decided it was time to establish its own affiliate in Germany. When I presented my business plan, the initial focus was on the level of investment required. My point was clear: if we want to succeed and have a significant impact on sales and organizational growth, Germany is a market where we need to invest fully. To be a truly European and global company, having a direct presence in Germany is non-negotiable.

Over the past two years, we have recruited over 44 new employees across Germany, primarily in sales, marketing, and medical roles, creating an extremely lean organization. We deliberately avoided heavy administrative and back-office functions—I am effectively my own CFO, CHRO, and head of regulatory/legal. This lean structure reflects my sales-driven mindset and ensures resources are focused on growth rather than bureaucracy.

Last year, I had the privilege of founding the German affiliate in Düsseldorf, registering it as a commercial entity.

EF: What is your pitch to attract resources to the market? Why should IBSA prioritize investing a euro in Germany over other regions?

MB: If you want to be a major player in Europe, you must invest in Germany. While the return on investment may not match that of rapidly growing markets, investing in Germany builds a strong reputation and establishes a solid foundation for long-term business success.

Within just a year or two, we have seen a significant increase in awareness. People are now recognizing IBSA, a name they may not have been familiar with before. This underscores the importance of establishing a strong foundation and presence in Europe. As we know, the "big five" European countries play a pivotal role, and it is essential to have a presence and invest in these key areas.

EF: Could you share insights on how IBSA's portfolio is balanced across reproductive medicine, orthopedics, endocrinology, and aesthetics? Additionally, how do you determine which therapeutic areas to prioritize and introduce to the German market?

MB: We offer a complete portfolio in reproductive medicine, covering every phase of treatment. From hormone stimulation in the initial phase, infection management, and medical support by medicines at embryo transfer to achieving live births, we have all the essential products. Additionally, we provide surrounding solutions, enabling us to deliver a holistic portfolio. This segment currently represents the 2nd largest stake in our business. Our biggest business is the derma aesthetic business (Hyaluronic acid products for injections), where IBSA is one of the leading companies worldwide with its own production site in South Italy. Our team works closely with fertility centers across Germany, which include 154 private and university-owned clinics. Another key segment, though smaller in size, is endocrinology. This includes drug treatments for conditions such as hypothyroidism

This year, we launched two completely new business units. First, we revamped our derma aesthetics strategy. Previously, products were sold through a distributor to a wide range of clients. Now, we focus exclusively on plastic surgeons and aesthetic dermatologists.

The other new business unit is orthopedics, which we built entirely from scratch. Currently, fertility and dermatology/aesthetics are our largest sales segments. Orthopaedics is our fastest-growing segment, and while endocrinology is smaller, it is critical for strengthening the company's reputation and expanding its footprint in this area.

EF: Has the National Pharma Strategy enhanced the operational environment for businesses in Germany?

MB: When it comes to digitalization, Germany remains significantly behind. Right now, we are still relying on outdated practices like handwritten prescriptions (e-prescriptions developing at a low level so far) and printed documentation. What we need is a top-down initiative from the government to establish a comprehensive structure for digital patient records. This system should ensure that every patient has a unified itinerary of their medical history, accessible across all providers, whether it's a doctor visit or a specialist consultation.

EF: As you celebrate IBSA´s 40th anniversary, what message would you like to share with your team about their contributions and the impact of your work in Germany?

MB: Our company has grown rapidly and now has a solid global footprint, with a presence in South America, Asia, and beyond. We have become a true global player.

What makes our company truly unique, though, is our culture. Despite the rapid expansion—we now have nearly 2,400 employees worldwide—our company culture remains strong. Here in Germany, we're a small team of just 44, but we are accelerating. We are on track to triple our sales this year, starting from a smaller base.

> "We are part of a fast-growing company, but we remain committed to maintaining our unique culture and mindset. We believe in the power of entrepreneurship within every individual, and that's what drives our success."

Dr. Richard Ammer

MEDICE

Chief Executive Officer,Germany

EF: Could you provide a brief history and context about the organization? Could you share an overview of its evolution and how it has grown into the family it is today?

RA: MEDICE was founded in by my wife's grandfather Gustav Pütter in 1949. After his sudden passing in the 1970s, his son, took over leadership. His primary focus was on implementing ICH guidelines.

In third generation, Katja joined MEDICE in 2001. I followed in 2003, and together, we have been managing owners for nearly two decades.

With our background in analyzing Germany's pharmaceutical industry and growth strategies, we chose to focus on specific therapeutic areas and niche indications where we could compete effectively with major pharmaceutical companies. We built a broad portfolio of innovative products while also maintaining a strong presence in the substitution market. In addition to our RX business, we have a significant presence in the primary care and consumer care segments. MEDICE is now ranked among the top 15 pharmaceutical companies, with a strong position in both pharmacies and general practice.

Our portfolio has expanded significantly through in-house developments, leveraging proprietary technologies. One of our key innovations is pellet technology for modified-release substances, which has been instrumental in the growth of our ADHD franchise. Therapists recognize modified-release stimulant medication as a therapeutic advantage, as previous pharmacological treatments primarily consisted of short-acting tablets.

With the introduction of modified-release capsules, parents retained control over the medication, eliminating the need for children—who often struggle with self-organization—to take a second dose during school hours. This advancement, which ensures coverage throughout the school day, has been a breakthrough in ADHD pharmacotherapy and has helped us secure a market-leading position in Europe.

Another key area of expertise that aligns with my background as a medical doctor is renal care. We have successfully introduced biosimilars to the market and recently launched an innovative HIF stabilizer for treating anemia in chronic kidney disease (CKD) patients. This represents a paradigm shift by offering an oral treatment option for anemia in CKD.

In the primary care and consumer care segments, we have built a "House of Brands" covering four key therapeutic areas: Women's Health, Cough & Cold, Skincare, and Gastroenterology. These brands are effectively positioned for pharmacists and general practitioners, ensuring strong market recognition.

> "A defining aspect of our company is full integration, we conduct our own research, clinical and analytical development, and manufacturing. Our products are produced entirely in Germany."

Unlike many generic manufacturers that claim "Made in Germany" while outsourcing key processes, we oversee the entire production chain, from active pharmaceutical ingredient (API) manufacturing to the formulation of solid, liquid, semi-solid, and injectable products.

EF: How do you envision the landscape in Germany in 2025, and what are the key priorities on your agenda?

RA: Germany has just held its elections, yet healthcare does not appear to be a priority in any political program. However, demographic shifts are forcing Germany to reconsider how to finance its healthcare system. Currently, we spend approximately €250 billion on medications and pharmaceuticals, including VAT and distribution margins, but hospital expenditures are nearly twice that amount. Given this, it is essential to examine what is happening in the hospital sector.

The hospital sector, in particular, requires significant restructuring. Some adjustments have been made to the framework for primary, secondary, and tertiary care, but challenges remain. I was trained under the DRG system, which emphasized early patient discharge. Now, the approach is shifting once again. When I returned from the U.S. to work in German hospitals, I noticed strong differences—while my ward remained empty over the weekend, my colleagues' wards were overcrowded. This highlights the imbalance in patient distribution and the urgent need for specialization.

In the pharmaceutical sector, there is a pressing need to rethink and revolutionize the system. The current tendering process for generics in Germany is not viable for manufacturers based in Europe. The "winner-takes-all" approach in health insurance tenders frequently favors manufacturers from the Far East. For example, many German health insurance funds source their medicines from companies that maintain only a minimal presence in Germany—primarily to oversee supply chains and handle final product releases. This allows medicines produced entirely abroad to be labeled as "Made in Germany" with just a single signature. This practice is misleading to consumers and should be addressed at the European Commission level. However, strong lobbying from generic associations has so far prevented meaningful reform.

Another issue is the significant cost disparity between Europe and countries like India. In Germany, producing a single medication carton costs around 30 cents, whereas in India, it costs less than one cent. As a result, European manufacturers struggle to compete in tenders where a month's supply of medication is expected to be priced at less than 17 cents. Over time, price regulations have driven costs so low that domestic production has become unsustainable, leading to increased reliance on manufacturers in the Far East.

The second major challenge is the fixed price scheme, where therapeutic equivalent medications without IP protection are grouped into a single category and subjected to strict price regulations. Over time, this has led to severe price erosion. I describe this as an "asymptotic approach to zero," where annual recalculations continuously drive prices lower. While this may be manageable in the first five years of a drug's lifecycle, after more than 20 years, it has pushed prices to unsustainable levels, making it nearly impossible for European manufacturers to compete. As a result, production has increasingly shifted to the Far East.

Given these challenges, our strategy has been to shift away from competing with large generic companies and instead focus on niche markets and innovation. This approach has been well received, particularly with the introduction of our new HIF stabilizer for anemia treatment. However, bringing innovative therapies to market requires navigating complex health technology assessments (HTA) for reimbursement and pricing.

Currently, the European regulatory landscape is highly fragmented, with each country enforcing its own set of requirements. For example, Germany demands a 5,500-page dossier, costing approximately €1 million, to assess added benefits versus a comparator. In contrast, the UK's NICE system requires a different methodology with only 400 pages, while Switzerland and other European countries each have their own distinct processes.

A more harmonized system would not only speed up approvals but also help establish a more justified and consistent pricing structure across the region. My concern is that without such alignment, we will continue to see fragmented pricing across countries, fueling parallel trade. This allows intermediaries to exploit price discrepancies by purchasing medicines in lower-cost regions and reselling them at higher prices elsewhere. Such inefficiencies create artificial shortages in some areas and oversupply in others, all driven by unnecessary bureaucracy.

EF: Could you share more about your footprint in digital solutions and how you are integrating them into the overall Medice Health Family?

RA: In addition to pharma and sustainability, we see digitalization as a key driver in healthcare and beyond, creating new value-driven business opportunities. We are currently in the midst of a transformation, which is why, alongside our sustainability initiatives, we have also established Medigital. While the name may not translate easily into English, it reflects our focus on media and digital health solutions.

Dr. Stefan Koch

Klosterfrau AG
Chief Executive Officer, Germany

EF: Could you give us an overview of the history of the company and how it evolved into the company it is today?

SK: The true story begins in 1775 in Brussels, where a young girl named Maria Clementine Martin was born. She became a nun and worked on European battlefields during the wars of that time. To this day, the nun symbol remains a hallmark of our brand.

After World War II, Klosterfrau was transformed into a modern OTC Company; we expanded our product portfolio and acquired later other companies, such as FARCO-PHARMA and Maria Galland Paris, a luxury cosmetics brand.

Especially after the Covid pandemic, we have undergone a significant transformation. By focusing on our roots and strengths, we have become one of the fastest-growing OTC companies in Germany. The journey so far has been incredible, and we are optimistic about continuing this success in the years to come.

> "We have a rich heritage, a meaningful story, and a clear purpose. I focused on reconnecting with these roots and realigning the company with its original mission: producing medicines and products that genuinely help people."

For us, it is about being more than just a business. We are building something holistic that goes beyond the typical definition of a company.

Our sustainability and social responsibility initiatives further set us apart. They are integral to who we are and create a sense of pride and belonging among our team.

EF: What is your perspective on the current pharmaceutical landscape, particularly in the OTC segment?

SK: Germany's pharmaceutical industry is closely tied to its pharmacy network. Ten years ago, there were around 22,000 pharmacies across the country, serving a population of 80 million—approximately one pharmacy for every 4,000 people. However, the introduction of electronic prescriptions, which are digitally transmitted directly to pharmacies, has opened the door to mail-order pharmacies.

This shift has led to a dramatic decline in the number of physical pharmacies. From 22,000 ten years ago, the number has already fallen to 17,000—a loss of 5,000—and this trend is expected to continue. Estimates suggest that the total could drop to between 12,000 and 14,000 in the upcoming years.

This reduction will have profound consequences. In major cities like Berlin, Hamburg, and Cologne, access to pharmacies remains sufficient. However, people may need to travel 20, 30, or even 40 kilometers to obtain their medications in rural areas. In response, the government is likely to explore alternative solutions.

EF: What do you think about the pharma national strategy and the way it is shaping Germany?

SK: As a pharmacist by training, I have a deep connection to the idea of Germany as the «pharmacy of the world.» This heritage ties closely to the nation's potential to lead in pharmaceutical innovation.

For Germany to reclaim this leadership, it hinges on several factors: fostering an environment conducive to foundational research, encouraging innovation, and ensuring universities and institutions can develop new products without immediately transferring them abroad, particularly to the U.S.

While I see many changes happening in Germany, I believe this is a pivotal moment. With the car industry on a decline, the healthcare sector has become a critical focus for the government. I sense a strong commitment to creating an environment that drives innovation and positions the healthcare sector as a growth area.

EF: Could you elaborate further on the various brands in your portfolio and how the strategic acquisition of numerous companies over the years has contributed to building and strengthening this portfolio?

SK: It is quite a significant story. Klosterfrau operates as more or less a foundation, with its portfolio currently encompassing four business areas with four different companies. These include Klosterfrau FARCO-PHARMA, a medical device company; Maria Galland Paris, in the luxury cosmetics industry; and Artesan Pharma GmbH, a 3rd party CDMO which produces Klosterfrau products as well.

When people think of Klosterfrau, they primarily associate it with OTC products. While the companies within our group are diverse, the focus has often been on OTC products that were acquired around 20 years ago. This portfolio includes well-known market leaders in Germany, such as Neo-Angin, Bronchicum, and Nasic. However, after the acquisition phase, there was a noticeable slowdown in product innovation and development. The company maintained its focus on existing products, which was profitable, but there were no new launches for nearly a decade.

In recent years, we have dramatically shifted our strategy. Drawing from my 22 years of experience in the pharmaceutical and medical device industry, I adopted a faster, more agile approach—one that embraces experimentation, learns from failures, and moves forward quickly.

Now, we are heavily focused on innovation and expansion. This year alone, we will launch seven or eight new products—probably the highest number among OTC companies in Germany. Realistically, I expect only two of these to achieve significant success.

EF: What message would you share to inspire reflection on the journey so far and guide the vision for the future?

SK: In Germany especially, with the economy declining and so many challenges ahead, people seem more nervous and less courageous. The funny thing is, when we look back 20 years from now, we will likely say, "Those times were easier." It is all about perspective.

I firmly believe that change is easier in a dynamic, shifting world than in a stable, unchanging one. In stable times, people are less inclined to adapt. We have achieved so much during the last few years. We have built a stable, strong, and modern organization, we have generated a full pipeline of new products, and we are investing a lot of money in our production sites. So, I believe we can look to the future with great optimism.

The saying: "*Health is not everything, but everything is nothing without health.*" It captures a fundamental truth, and it resonates deeply in the pharmaceutical industry. Whatever we do as a company, we must always remember our duty—to produce and deliver the best products that keep people healthy.

Chapter 4

MedTech

Increased Value: A new Perspective on Healthcare Transformation

"Germany has the potential to lead healthcare system improvements. Germany's data, which offers unmatched insights to 80 million people. Real-life screening results could be analyzed within two years." **Wouter Peperstraete**, *General Manager DACH, Hologic*

MedTech Powerhouse Germany: Building Value through Technology

Germany is not only Europe's largest healthcare market, it is also a cornerstone of the global MedTech industry. Home to world-class hospitals, scientific institutions, and a thriving innovation ecosystem, the country plays a crucial role in advancing medical technologies that shape healthcare far beyond its borders. But today, that leadership is being tested by mounting pressures: rising costs, an aging population, and an urgent need for system-wide transformation.

At the heart of this evolution is a new mandate for MedTech players: to move beyond products and devices and become strategic partners in delivering value. Across the country, leaders in diagnostics, monitoring, and digital health agree that healthcare transformation in Germany has to become a coordinated, outcome-driven journey.

Value-Based Healthcare as System Opportunity

"Value-based healthcare (VHBC) takes different forms in every country. Since every healthcare system is distinct, it must always have a local connotation. The German age pyramid is one of the most distorted. We know that the amount of care that must be given will grow rapidly over the next 20 to 30 years. We also know that budgets will have difficulty keeping up with this exponential increase. Value-based healthcare can help with it. The issue is how to provide the optimal care for an increasing number of patients. Homecare treatments, combined with a VBHC approach, will be an essential way to tackle this challenge. Home care is not only the most economical option, but also the type of treatment patients prefer." **Luca Valsasina,** General Manager at VitalAire in Germany and Romania

"The shift towards value-based healthcare models, such as Hybrid Diagnosis-Related Groups (DRGs), is reshaping the healthcare landscape. These models incentivize efficiency, quality of care, and positive patient outcomes rather than service volume (fee for service). For Beckman Coulter, this underscores the importance of demonstrating the clinical and economic value of our diagnostic solutions. We provide evidence that our technologies contribute to better patient outcomes, reduce hospital stays, and optimize resource utilization." **Roberto Godoy,** Managing Director North and Central Europe, Portugal and European Distribution, Beckman Coulter Diagnostics.

"Healthcare systems, including DACH, are struggling with rising demand, costs, staff shortages, and financial limits. Climate change adds pressure on health systems and affects consumer behavior. Meanwhile, technology and AI are transforming hospital and home care. In this area of tension, we are fully focused on how we can help people take better care of their health work with healthcare providers to overcome these barriers and use innovation to accelerate diagnosis to support better patient outcomes." Mikko Vasama, *Managing Director, Philips Health Systems DACH*

"At Hologic, the focus has always been clear: delivering value to society. This approach is evident in our Global Women's Health Index and how we combine expertise in scientific research, market access, and healthcare organization. We are invited to discussions to share insights, analyze data, and recommend strategies. We drive impactful changes in women's healthcare beyond just selling devices. We know how to make a real impact and are committed to leading the way." **Wouter Peperstraete,** *General Manager DACH*

THE MEDICAL TECHNOLOGY INDUSTRY IN NUMBERS

43 bn
medical technology market volume in Germany in 2023 (in EUR)

10bn
annual R&D spending of the German medtech industry (in EUR)

265.000
employees in the German medical technology industry

Source: health-made-in-germany.com

Women's Health and the Case for a Health Index in Germany

Despite being a global leader in medical technology, Germany still underperforms when it comes to advancing women's health. The recent Women's Health Study by the World Economic Forum and McKinsey shows that improving health outcomes for women is not only a public health priority but also a major driver of economic productivity. Yet progress remains uneven.

As **Wouter Peperstraete** at Hologic, explained, *"A common challenge is that many politicians see Germany's healthcare system as one of the best globally and question the need for further changes. However, our German Global Women's Health Index highlights areas that need attention, especially in organized screening and prevention. While accessibility, poverty, and life security for women in Germany are less of a concern overall, some populations still face significant issues. One major gap lies in prevention efforts, where participation rates still need to be higher."*

The index can help compare progress across regions, track screening rates, and identify where investment is most needed. Germany has the infrastructure, medical expertise and innovation ecosystem to lead in this area. Tools like AI-supported mammography are already transforming early detection and easing the burden on overstretched healthcare professionals.

However, *"on the data side, Germany faces significant challenges. Unlike other countries, population health data is not centralized. Insurance companies keep data to themselves, and cancer registries report at a state level, creating a fragmented system. Real-life screening results could be analyzed within two years, unfortunately, this isn't happening. Germany needs to leverage its data to evaluate the impact of changes or learn from them efficiently."* sustains Peperstraete. Only with the right national frameworks in place, Germany can turn data and diagnostics into better care for women and set a global example for integrated, equitable healthcare.

Smarter Care: AI, Talent Shortages, and the Future of Healthcare Delivery in Germany

Germany's healthcare system is under extraordinary pressure. A perfect storm of workforce shortages, rising demand, financial constraints, and policy transitions is driving a rethinking of how care is delivered, funded, and supported. The question at the heart of this transformation: how can innovation enhance healthcare without compromising the human touch?

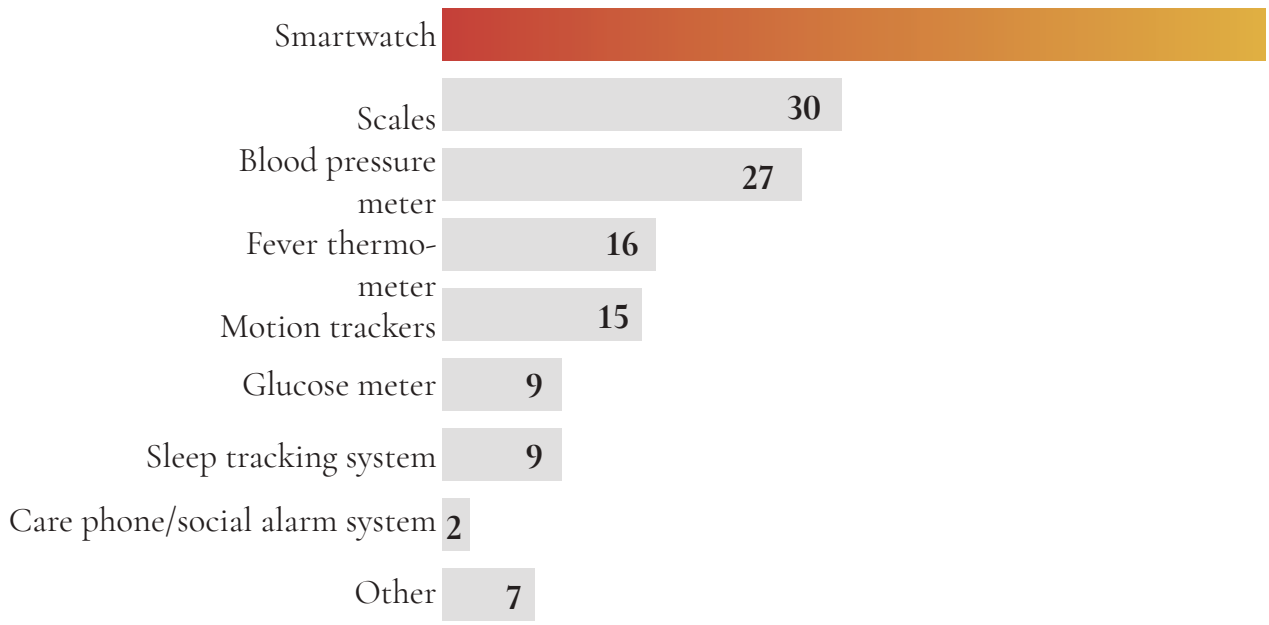
Across the country, hospitals are operating under capacity, not due to lack of beds but lack of people. In Berlin, for example, only 85% of beds are currently usable because of staffing limitations. Meanwhile, financial and demographic pressures are intensifying, making the need for smarter, more sustainable models increasingly urgent. In response, the sector is turning to automation, artificial intelligence (AI), and data-powered systems to help reconfigure roles, improve outcomes, and safeguard system resilience.

Talent Shortages as a Catalyst for Innovation

The shortage of healthcare professionals is not just a constraint; it's become a catalyst for transformation. **Mikko Vasama,** Managing Director of Philips Health Systems DACH, highlights a significant shift: "*One of the industry's most pressing concerns is the staffing shortage in customer service.*" And detects that at the same time "*There is a growing need for advanced solutions that generate more diverse data types. We aim to develop solutions, products, and an ecosystem that enables customers to operate efficiently despite workforce limitations.*"

VitalAire's General Manager for Germany and Romania, **Luca Valsasina** echoes this by noting that home care, paired with technology, is not just cost-effective but also a way to alleviate clinical workload: "*Telemonitoring is one technology that can significantly improve patient care without requiring many doctors or nurses to visit patients' homes daily.*" These perspectives underscore how the workforce crisis is pushing providers and companies alike to rethink care pathways and invest in scalable, digitally supported solutions.

MOST FREQUENTLY USED SMART HEALTH DEVICES IN GERMANY IN PRESENT



Source: eHealth Report Statista (2020)

The Rise of Applied AI in Healthcare

AI has quickly evolved from buzzword to operational backbone in many areas of care. At Philips, innovations in radiology are already delivering real-world impact. *"Our latest technology can enable scans to be completed up to three times faster, significantly cutting scan times while maintaining exceptional image quality,"* said Vasama. Their dual-AI engine improves image sharpness by 80%, enhancing diagnostic accuracy and patient throughput.

At Beckman Coulter Diagnostics, AI is helping optimize lab workflows and integrate predictive analytics. *"AI is revolutionizing laboratory operations by automating routine tasks and predicting maintenance needs. Integrating AI and machine learning into our diagnostic tools allows for advanced data analysis and predictive analytics,"* said **Roberto Godoy**, Managing Director North and Central Europe, Portugal and European Distribution, Beckman Coulter Diagnostics.

Dr. Frank Wartenberg from IQVIA emphasizes AI's role in turning data into actionable insight. *"In the healthcare industry, data-driven decision-making is very crucial," he said. "For many years, we have incorporated AI and machine learning into many of our client solutions. For instance, we are collaborating with the University Hospital of Bielefeld's heart and diabetes center, Bad Oeyenhausen, to provide the surgeon with real-time assistance to maximize the patient's outcome."*

Beyond hospitals, IQVIA is working with sick funds under financial stress, digitizing claims processes and even administrative tasks for midwives: *"We are assisting the sick fund to make better decisions and operate more effectively. The healthcare system as a whole needs fresh concepts and new ideas by brave minds using technological progress."*

A Hybrid Future: Keeping the Human in the Center

Despite the rapid pace of technological advancement, healthcare leaders in Germany agree on one essential point: AI is not here to replace clinicians but to empower them. The future of healthcare will be hybrid, blending intelligent automation with human care to meet growing demand without compromising quality.

Luca Valsasina, highlights the importance of filtering telemonitoring data to ensure clinicians focus on what matters most. *"In its most basic version, telemonitoring might be problematic. Doctors need someone who can help them with technical matters or less critical medical alerts. The most effective way to care for patients in the healthcare system is to combine medical, professional, and technological expertise with someone in between who coordinates everything."* he explains. Showing that without the right support, technology can become a burden rather than a benefit.

Philips shares a similar view. Their AI-driven solutions aim not to substitute healthcare professionals but to free up their time, helping them focus more on patient care and less on routine tasks. As **Mikko Vasama**, noted, *"Navigating these changes requires strong partnerships. Working closely with hospitals on the principles of collaboration allows us to adapt to the evolving landscape and develop solutions that provide the necessary flexibility."*

The German healthcare system, under pressure from workforce shortages and financial constraints, is discovering that innovation is not about disruption for its own sake. Whether it's co-developing AI tools with hospitals or digitizing midwives' workflows, smart care is about reinforcing human expertise, not replacing it. The path forward is not fully digital or strictly traditional. It is hybrid. And at the center of that model must be the people: clinicians, caregivers, and patients, all supported by technology that enables them to do their best work.

Wouter Peperstraete

Hologic
General Manager DACH, Hologic

EF: Could you give us an overview of the current priorities on your agenda and what we can expect from Hologic in Germany in 2025?

WP: In 2025, our primary focus will remain on Women's Health, which makes up 80% of our business. We also have a molecular diagnostics segment contributing to HIV patient testing and the transplant panel. These efforts aim to broaden our assay menu on the existing platforms to increase consolidation and efficiency, but Women's health remains our core activity. We see a mix of optimism and challenges ahead, particularly with changes in the German healthcare market. The government has initiated a hospital reform to reduce hospital beds and shift some interventions to day clinics or simpler procedures to keep the system sustainable. However, with the government transition and policy uncertainties, how 2025 will unfold regarding reimbursement levels and hospital operations needs to be clarified. Hospitals are expected to be categorized into tiers A, B, C, and D, but details are still being finalized.

For Hologic, which specializes in breast health, the landscape is evolving. Germany's organized screening programs and designated breast centers play a key role, but questions remain about how these centers will link to local hospitals for chemotherapy and follow-up care to provide fast and accurate patient treatment.

Meanwhile, new approaches like hybrid DRGs are slowly gaining traction, which we're closely monitoring as part of this evolving environment. Hybrid DRGs are used to group hospital interventions, combining traditional inpatient care with outpatient or day clinic procedures. For example, a patient might spend part of the day under supervision but go home afterwards. This system creates a single reimbursement rate by averaging costs, even though specialized interventions like ours are more expensive. This could result in a choice where the best patient treatment is not always favored compared to the financial profits.

In Germany, implementing reimbursement regulations like hybrid DRGs can be slow, but some changes happen rapidly, sometimes within three months. This fast pace has challenged us, even with our dedicated market access teams, as it's harder to predict changes. Still, these shifts create opportunities. For instance, hybrid DRGs could allow us to enter markets we previously couldn't, such as polyps or myoma removal, where our devices are costly. Balancing these uncertainties is challenging, especially for leaders who prefer clear predictions, but it also brings growth potential. We are actively engaged in the laboratory environment in Germany, where we see challenges not just in reimbursement but also in the financial stability of labs and the timing of testing.

On a more positive note, we're following the TOSYMA trial in breast health, the world's largest study comparing 2D and 3D digital mammography. Alongside extended age screening, we expect 3D tomosynthesis to gain wider adoption due to its advanced technology. We are well-positioned with strong 3D imaging technology and AI-powered software that supports efficient image acquisition and interpretation. By 2025, the study's final results should be published, requiring the German government to make key decisions on integrating 3D mammography into screening programs. This will impact investments in mammography systems, as hospitals will need devices capable of both 2D and 3D imaging to ensure they are future-ready when 3D becomes part of the reimbursed screening algorithm.

EF: Could you give us an example or elaborate on how you are pushing the Women's Health Agenda in Germany beyond the physical portfolio?

WP: A common challenge is that many politicians see Germany's healthcare system as one of the best globally and question the need for further changes. However, our German Global Women's Health Index highlights areas that need attention, especially in organized screening and prevention. While accessibility, poverty, and life security for women in Germany are less of a concern overall, some populations still face significant issues.

One major gap lies in prevention efforts, where participation rates still need to be higher. Programs like cervical and breast cancer screenings, where we are market leaders, require much more focus and a long-term vision. Insurance companies often assess benefits over a three-year portfolio, which complicates showing the long-term value of screenings that prevent cancer over 10-20 years. We aim to address these issues by encouraging better communication and responsibility for inviting women to screenings. This aligns with our goal of improving Women's Health outcomes. Through the activities we organize with Forum Frauengesundheit, we plan to continue this work, likely hosting two events in 2025. Our primary objective remains to ensure Women's Health stays on the political agenda.

EF: How are you using AI and technology to enhance your operations and bring treatments to patients faster, internally, and patient-facing?

WP: Ensuring compliance with patient safety and respecting the responsibilities of doctors, radiologists, and gynecologists is essential. We need to align their practices with the logic of our proposals. AI is designed to assist in faster decision-making, enabling radiologists or cytologists to focus on specific areas rather than scanning entire images.

The future of AI in healthcare, particularly in Germany, faces challenges. There is a growing strain on the healthcare workforce globally, and Germany's system will likely demand solutions sooner than others to maintain the current quality and access levels. AI could help by identifying negative cases, allowing healthcare workers to focus on higher-risk patients, such as those with dense breast tissue or lifestyle-related risks. However, this evolution depends on legislative changes. Legislation must clarify acceptable sensitivity and detection rates for AI systems, acknowledging that no AI is 100% accurate and mistakes will occur. For example, using AI to clear 60% of mammograms as negative would still involve some errors. Striking a balance between AI investments, maintaining doctors' roles, and ensuring fair compensation is critical, just as we balance our position in the medical device market. While workforce pressures might accelerate AI adoption, proper legislation is crucial to guide its implementation and address these challenges effectively.

EF: Is there any initiative Hologic is working with to address this medical education and training in women's health?

WP: Our focus is on improving the experience for women during mammography, ensuring they feel comfortable. A growing trend is using real-life data, where AI integrated into mammography systems can immediately flag high-risk cases. For example, suppose a patient's scan shows a potential issue. In that case, the radiologist can prioritize it, allowing the patient to stay for further diagnostics, such as a biopsy, instead of going home uncertain. This approach helps patients get quicker clarity, whether it's cancer, something benign, or something requiring further investigation. In Germany, the process currently needs to be revised. Screening images are often reviewed one or more days late by radiologists. However, with "AI" technicians, MTAs in Germany could immediately assess breast density and decide whether a 2D or 3D mammogram is more appropriate. If AI identifies a high-risk case, the patient can immediately proceed to additional diagnostics on the same visit.

Regulations require biopsy and pathology results within a couple of weeks to one and a half months. We aim to shorten this period so that high-risk patients can be identified quickly and prioritized for further care.

On the data side, Germany faces significant challenges. Unlike other countries, population health data is not centralized. Insurance companies keep data to themselves, and cancer registries report at a state level, creating a fragmented

system. If I were in politics, I'd emphasize the immense potential of Germany's data, which offers unmatched insights to 80 million people. Real-life screening results could be analyzed within two years, compared to smaller countries like Belgium or the Netherlands, which may take a decade. Germany has the potential to lead healthcare system improvements. For instance, the NHS excels in using data to drive decisions, investing in more expensive technology if it saves time and improves outcomes. Germany, the largest European country, should aim to match that efficiency level, using its data to analyze performance quickly and make real-time improvements.

EF: If you had to address the World Health Summit from a women's health perspective, what would your message be?

> **"The key message was clear: even in Western societies, leaders cannot treat women's health as an accomplished fact. Significant delays still exist in approving simple interventions that could improve women's lives, especially when compared to the faster approval processes for treatments like prostate cancer."**

Legislators need to recognize that men and women have different healthcare needs and ensure that policies reflect those differences, not by pitting genders against each other but by acknowledging and addressing the unique challenges women face.

Society has evolved, and the role of women has changed significantly. Today, women work as much as men, contributing equally to their families' economic well-being. With many expected to work into their mid-60s or beyond, ensuring women's health isn't just a social responsibility; it's an economic necessity. Women's health must be central to decision-making, reflecting their growing societal role and value.

When I started in the medical device industry, there was skepticism about companies prioritizing profit over value. But at Hologic, and even in my prior roles, the focus has always been clear: delivering value to society. We ask how we can improve lives and ensure people live healthier for longer. This approach is evident in our Global Women's Health Index and how we combine expertise in scientific research, market access, and healthcare organization.

Roberto Godoy

Beckman Coulter Diagnostics
Managing Director North And Central Europe, Portugal and European Distribution,

EF: Beckman Coulter has a significant presence in Germany. How would you describe the company's footprint and portfolio here, and what trends have you observed in the German market?

RG: Germany is a cornerstone of our operations, reflecting our commitment to excellence and dedication to meeting the needs of one of Europe's most advanced healthcare systems. Our footprint here includes a comprehensive portfolio of diagnostic solutions—from high-throughput analyzers to specialized reagents and innovative software platforms.

We've established strong partnerships with leading hospitals, laboratories, and research institutions. This collaboration keeps us at the forefront of technological advancements and ensures our products align with the evolving demands of healthcare providers.

In terms of trends, there's a growing emphasis on personalized medicine and precision diagnostics. The integration of advanced technologies like artificial intelligence and data analytics is becoming increasingly important for enhancing patient outcomes. Additionally, there's a heightened focus on solutions that improve laboratory efficiency and streamline workflows.

Germany's regulatory environment is influential, often setting standards that impact the broader European Union. This requires us to be proactive in compliance and quality assurance, ensuring our products not only meet but exceed regulatory expectations.

EF: How would you describe Germany's strategic importance to Beckman Coulter on a global scale?

RG: Germany's strategic importance cannot be overstated.

> "As Europe's largest economy and a leader in medical technology, it plays a pivotal role in shaping healthcare trends and standards. Success in Germany enhances our global reputation and provides valuable insights that inform our strategies in other markets."

Excelling here demonstrates our ability to meet the highest standards of excellence, reinforcing trust with customers worldwide.

Moreover, Germany often leads in adopting new healthcare models and technologies. Engaging effectively allows us to stay ahead of industry developments, adapt to emerging needs, and bring innovative solutions to other regions.

EF: Can you elaborate on Germany's influence within the broader EU framework and its implications for your role overseeing multiple European markets?

RG: Germany's influence within the EU is significant, especially in healthcare regulation, policy-making, and standard-setting. Developments here often have a ripple effect across the continent.

In my role overseeing multiple European markets, this approach enables us to harmonize operations and ensure our products meet diverse regional needs while adhering to consistent quality and compliance standards. Additionally, Germany's innovation leadership fosters opportunities for cross-border collaborations, enhancing our offerings throughout Europe.

EF: Reimbursement models are rapidly evolving. How do innovations like Hybrid Diagnosis-Related Groups impact Beckman Coulter's operations?

RG: The shift towards value-based healthcare models, such as Hybrid Diagnosis-Related Groups (DRGs), is reshaping the healthcare landscape. These models incentivize efficiency, quality of care, and positive patient outcomes rather than service volume (fee for service).

For Beckman Coulter, this underscores the importance of demonstrating the clinical and economic value of our diagnostic solutions. We provide evidence that our technologies contribute to better patient outcomes, reduce hospital stays, and optimize resource utilization.

We've invested in health economics and outcomes research to quantify our products' benefits. By aligning our innovations with value-based care goals, we strengthen partnerships with healthcare providers and support them in achieving their objectives.

EF: Artificial intelligence is making waves in diagnostics. How has AI been integrated into Beckman Coulter's operations since the 2022 acquisition, and what does the future hold?

RG: AI is revolutionizing laboratory operations by automating routine tasks and predicting maintenance needs, helping laboratories improve efficiency, reduce errors, and optimize resources.

Our innovations at Beckman Coulter rely on technology. We leverage automation and clinical informatics to enhance lab efficiency, reduce human error, and speed up processes — all of which enhance the patient experience. Integrating AI and machine learning into our diagnostic tools allows for advanced data analysis and predictive analytics, especially of large data sets and when time is of the essence, like in emergency rooms, minimizing uncertainty and helping clinicians make quicker, more accurate, better-informed decisions.

AI integration aligns with our broader vision of digital transformation, combining advanced diagnostics with data analytics to open new avenues for improving global healthcare outcomes.

EF: What steps must be taken today to create a transformative future for diagnostics, and how can investment be attracted to advance healthcare accessibility?

RG: Creating a transformative future for diagnostics requires a multifaceted approach. Sustained investment in research and development is essential to continue innovating in molecular diagnostics, point-of-care testing, and digital health solutions, always having the patient at the center.

Collaboration is key. Partnering with academic institutions, healthcare providers, and industry peers accelerates innovation and ensures new technologies address real-world clinical needs.

To attract investment, we must demonstrate the tangible impact of advanced diagnostics—improving patient outcomes, enhancing operational efficiency, and contributing to healthcare cost savings. Providing robust health economics data and real-world evidence makes a compelling case to investors and policymakers.

Healthcare accessibility is critical. Developing scalable, cost-effective solutions that maintain high quality is essential for reaching underserved populations. Leveraging technologies like telemedicine and mobile health platforms can extend diagnostics beyond traditional settings.

Engaging with regulators and policymakers to create a supportive environment is also important. Clear regulatory pathways and favorable reimbursement policies encourage innovation and investment.

EF: In 2025, Beckman Coulter will celebrate 90 years of legacy. What milestones stand out to you as part of this celebration?

RG: As we approach our 90th anniversary, we're not only reflecting on past achievements but also embracing the future, dedicated to improving healthcare through innovation and excellence.

While it is challenging to forecast the future in such a fast-evolving industry, Beckman Coulter Diagnostics is a proud member of Danaher, a global science and technology leader that seeks to be a key player in the future we create. In fact, Beckman Coulter Diagnostics embraces the group's aim to accelerate the power of science and technology to improve human health, and, to quote Rainer Blair, President and CEO of Danaher, at the most recent Danaher Summit: "We have to make the next 20 years a golden age for diagnostics—a critical catalyst, an enabler for what can be a revolution in healthcare—more accessible, more effective and more equitable. At Danaher, we're eager to build that future."

Mikko Vasama

Philips Health Systems
Managing Director, DACH

EF: Could you provide an overview of your current priorities and what we can expect from Philips in the DACH region this year?

MV: For Philips, it is all about providing better care for more people. Healthcare systems, including DACH, are struggling with rising demand, costs, staff shortages, and financial limits. Climate change adds pressure on health systems and affects consumer behavior. Meanwhile, technology and AI are transforming hospital and home care. In this area of tension, we are fully focused on how we can help people take better care of their health work with healthcare providers to overcome these barriers and use innovation to accelerate diagnosis to support better patient outcomes.

One of the industry's most pressing concerns is the staffing shortage in customer service. At a recent conference, I saw multiple hospital booths, not from vendors or companies like Philips but from hospitals themselves actively promoting their institutions to attract clinicians and nurses. This notable shift highlights the significant workforce shortages across the sector.

At the same time, there is a growing need for advanced solutions that generate more diverse data types. While this presents opportunities, it also poses challenges when combined with staffing shortages. Addressing this issue is a priority for us. We aim to develop solutions, products, and an ecosystem that enables customers to operate efficiently despite workforce limitations.

Beyond offering solutions and products, we also explore new operating and partnership models to better serve our care providers.

EF: Hospital reform brings significant uncertainty for hospitals. How do you view this situation, and how is Philips positioned to navigate these changes?

MV: Uncertainty is certainly a factor. From a timeline perspective, the reform has faced delays, and its evolution remains complex. There is clear guidance on which different categories of hospitals will handle procedures. University hospitals, for instance, will likely expand their role in certain procedures and specialized care due to increased patient volumes. This requires them to assess their need for greater flexibility. Meanwhile, central and smaller hospitals face an uncertain future. It is well known that the goal is to reduce the number of Hospitals significantly. At the same time, more procedures will be shifted from inpatient to outpatient care, making outpatient services increasingly important.

This transition also highlights the need for better connectivity. Hospitals and outpatient providers must establish networks to coordinate diagnosis and treatment efficiently. Patient pathways must be optimized, ensuring smooth transitions between facilities. Additionally, remote capabilities will play a key role in addressing workforce shortages. Diagnosing patients remotely and providing secondary consultations or second opinions will be essential in supporting smaller clinics.

> **“We are here to help hospitals through our innovation, enabling agility and keeping a patient-first mindset.”**

Beyond that, we also facilitate knowledge sharing, not only within Germany but across other markets. Coming from the Nordics, I often receive questions about how similar reforms were implemented in Denmark or Sweden. These discussions help hospitals navigate uncertainties by learning from international experiences.

Ultimately, navigating these changes requires strong partnerships. Working closely with hospitals on the principles of collaboration allows us to adapt to the evolving landscape and develop solutions that provide the necessary flexibility on both sides.

EF: Could you provide an overview of your presence in the country? Why is Germany strategically important to Philips?

MV: Germany is the beating heart of Europe, and we are here to help hospitals provide better care for more people through meaningful innovation. It has excellent research facilities, world-class hospitals, and a reputation for delivering precision innovation. Therefore, I can not emphasize the size and significance of the German healthcare market. It is one of the largest in the world and plays a crucial role for a global company like Philips. Financially, Germany is among our top markets, but its importance goes well beyond that.

Across the DACH region, Germany, Austria, and Switzerland, Philips has 4,500 employees. This includes commercial operations and significant investments in manufacturing and R&D. For example, our Böblingen campus is a major hub for patient monitoring, where we drive global innovation with deep expertise. Similarly, our Hamburg site has a long-standing focus on X-ray technology, and in Klagenfurt, Austria, we manufacture personal health products such as oral healthcare solutions. These investments reflect the strong emphasis on quality and expertise that Germany is known for.

Finally, an essential factor is the readiness of the German medical community to adopt new technologies. While technical and clinical excellence is critical, true innovation succeeds only when clinicians, nurses, and healthcare professionals embrace it. In Germany, we see strong engagement from our customers, who are willing to explore and implement new solutions in partnership.

All these elements—from market size and expertise to collaboration opportunities and a forward-thinking healthcare ecosystem—make Germany a strategically significant market for Philips.

EF: What upcoming innovations are you particularly excited about, and which do you believe could significantly impact healthcare?

MV: With over 130 years of history, innovation has always been at the core of what we do. One key trend is that innovation cycles are becoming shorter, with new advancements reaching the market faster due to rapid technological progress. At Philips, a significant portion of our R&D investment is directed toward technology, specifically software, data, and AI. We do this because these areas are critical to the future of healthcare. AI is a great example of how we are addressing major challenges, such as staffing shortages and cost pressures.

Additionally, AI is critical in enhancing image quality, making diagnostics more precise and reliable. We have a dual-AI engine, which delivers an 80% improvement in image sharpness, enhancing visualization for more confident and accurate diagnoses. Our AI solutions are designed to empower radiologists by providing deeper insights and enabling remote diagnostics.

Innovation at Philips is also about collaboration. As I mentioned earlier, we believe in co-creation with our customers. Instead of developing solutions in isolation behind closed doors, we work closely with healthcare providers to ensure that innovation directly addresses real-world needs. Even if we develop a solution with our customers that improves patient flow efficiency, regulatory requirements still impact implementation.

For example, we have developed a solution that enables intensive care units to operate more efficiently. However, German regulations mandate a specific number of staff in an ICU, which may no longer be necessary if a hospital adopts a more advanced, efficiency-driven approach. In such cases, regulators must evolve alongside industry advancements, working collaboratively with us and our customers to ensure regulations keep pace with innovation.

Luca Valsasina

VitalAire
General Manager Germany and Romania (Air Liquide Group)

EF: What goals did you set for yourself when you were appointed GM of Germany?

LV: Compared to my experience in Poland, Germany is a considerably larger market, and our range of activities is more extensive. My primary plan is to keep expanding the current initiatives in Germany while identifying new expansion opportunities. Additionally, I intend to accelerate the shift toward a value-based healthcare model that has been the cornerstone of Air Liquide's approach.

Value-based healthcare (VHBC) takes different forms in every country. My goal was to grow and transform our already broad portfolio of activities, thanks to VBHC's offerings while looking for selected new opportunities for development in new therapeutic areas.

EF: How do you want to broaden Germany's diversity or identify new development opportunities?

LV: Our history began with respiratory activities, such as oxygen in the hospital, progressed to oxygen at home, and subsequently developed a wide range of additional activities. Our primary business in Germany and most European nations is respiratory, which accounts for over half of our revenues. In Germany, we also have a lot of infusion activity, especially in diabetes. We have made significant progress in other, more specialized fields, such as immunological deficiencies and pAH.

Our activity is intensive care, which consists of more than 30 community care centers and involves extremely critical patients to whom we provide 24/7 intensive care.

EF: What do you think Germany's strategic importance is to such a large global corporation, and how would you convince headquarters to bring resources to Germany?

LV: The sheer size of the German market and its large population make it important. The Germany's healthcare system is highly fragmented but has strengths and challenges. In Germany, there are over 90 distinct health insurance providers. In contrast, most European countries only have one healthcare plan, which is the case in France, Poland.

On the one hand, Germany's fragmented healthcare system adds complexity because there are more negotiations, procedures, and ways to accomplish the same tasks. Still, it also gives you some flexibility because you can talk to those health insurance companies and be creative, suggesting new approaches that might be more difficult to implement in other nations with monolithic, more centralised systems. Germany's system is strong and flexible enough to innovate, which is essential for value-based healthcare. We want to promote and provide the German healthcare system with value-based healthcare, an innovative solution that benefits everyone.

EF: You spoke about introducing innovations with solutions that benefit all parties. What makes VitalAire's implementation of a value-based healthcare system so crucial?

LV: Value-based care aims to provide your patients with the finest results at the optimal price. This is essentially one of the primary answers to the healthcare system's problems going forward. We are all aware that the population will age and that chronic illnesses will become more prevalent in the years to come. Therefore, in the upcoming years, the number of patients, their complexity, and the level of treatment will all continue to increase. They do not appear very good when looking at age pyramids, of which the German age pyramid is one of the most distorted. We know that the amount of care that must be given will grow rapidly over the next 20 to 30 years. We also know that budgets will have difficulty keeping up with this exponential increase. Value-based healthcare can help with it. The issue is how to provide the optimal care for an increasing number of patients. Homecare treatments, combined with a VBHC approach, will be an essential way to tackle this challenge, which is why VitalAire is committed to value-based healthcare.

Since treating a patient at home is less expensive than treating them in a hospital, home care is not only the most economical option in many places these days but also the type of treatment patients prefer. Instead of remaining in the hospital or other care facilities, most people would rather stay at home. Here, we mix the most economical approach for the system with the best result for the patient. Thanks to modern technologies, we can all be innovative in caring for patients, even at home, and adopt methods that use fewer resources while producing excellent results. For instance, telemonitoring is one technology that can significantly improve patient care without requiring many doctors or nurses to visit patients' homes daily.

EF: Is VitalAire working on any projects to promote medical education and raise awareness among healthcare professionals about your products?

LV: In some ways, this is our daily business, as we frequently serve as the technological arm of healthcare professionals. For instance, we educate medical personnel about ventilators and their operation. We share our technological expertise on the device with medical professionals; we constantly strive to support the medical field with new technology, such as telemonitoring; however, these technologies will not replace medical professionals. They are the medical profession's enhanced capabilities.

In its most basic version, telemonitoring might be problematic because it actually generates a lot of alarms, such as "no data transmission" or "disconnected modem." It is inefficient and poor use of a doctor's time to spend time dealing with this type of data. The appropriate degrees of knowledge must be well-balanced. The most effective way to care for patients in the healthcare system is to combine medical, professional, and technological expertise with someone in between who coordinates everything.

EF: When you reflect on your career path, what are some of your proudest moments as the head of the company in your area, and what do you hope to achieve in the future?

LV: I am very proud of the team's commitment to the patients, their treatment, and the company's continued expansion.

> "The primary goal for the upcoming year is to continue the company's transformation into what we refer to as a therapy partner. The foundation of the value-based healthcare concept is a business that can serve as a therapy partner for both patients and medical personnel."

Chapter 5

Building the Basis for the Future

The new Pillars of Germany's Health Industry

"It's time to be bolder than ever, to think big and stay connected. Healthcare policy is also economic policy, and we need to connect the dots, plan for the long term, and act with a strong sense of urgency for what needs to be done today." **Urs Voegeli,** *Managing Director, J&J Innovative Medicine, Germany*

Navigating the Cost of Health

Germany's healthcare system is under mounting financial pressure. With one of the highest per capita health expenditures in the world, the country now faces a stark reality: rising costs, an aging population, and growing demand for advanced therapies are putting sustainability at risk.

Frank Wartenberg, President of IQVIA in Germany, points to a crucial inflection point: *"The cost of the sick fund in Germany will rise by about 1.84 up to 4.4 percent per person, plus an additional 0.2 percent for care. For a total sick fund rise in 2025 of 2.5% per person, which is a substantial increase."* According to Wartenberg, this sharp rise is prompting concerns from industry and health insurance leaders alike and identifies structural inefficiencies and uncontrolled expenses as key drivers of the problem. *"There are extraneous costs and expenses in the system that should not be borne by the insured members. They are funded by the solidarity system rather than by taxpayer dollars."* This, combined with rising labor and care costs in hospitals and long-term care facilities, is creating a system increasingly strained by demographic shifts. *"The largest factor is personal expense per patient in the aging society*," he said. *"Germany has some of the highest per capita spending for health in the world, but when it comes to the size of the difference between lifespan and healthy life, we do not have the best results per capita."*

Amid these financial pressures, access to high-cost therapies—particularly gene and cell therapies—is becoming a central policy challenge. Treatments that offer potentially curative outcomes often come with price tags in the millions, raising difficult questions about how to fund them fairly and sustainably.

Dr. Daniel Steiners from Roche highlights this dilemma using rare and common diseases as examples. *"If we consider a rare disease like Duchenne muscular dystrophy (DMD), where gene therapies are highly expensive, you might argue that the number of patients is small. However, these treatments could significantly reduce the long-term cost of care."* While this makes economic sense for rare conditions, he warns the stakes are even higher in more common diseases: *"The real challenge arises when we look at more common conditions, like Parkinson's, where cell and gene therapies and expensive treatments will affect a much larger population."*

The solution may lie in new financing models. *"We need to explore alternative reimbursement models, such as pay-for-performance schemes, where payments are spread over time instead of being made upfront,"* **Steiners** added. This approach, often referred to as outcomes-based or success-based reimbursement, is gaining traction.

One company already piloting this strategy in Germany is CSL Behring. *"We are currently negotiating pricing with the national health insurance (GKV-SV),"* said **Christian Wieszner,** Managing Director and Vice President of the DACH Cluster. *"Our proposal is a success-based annual payment model, which ensures predictable costs and aligns with the price of existing long-term treatments."* Under this model, reimbursement is staggered over multiple years and conditional on treatment success. *"This approach could make gene therapy more sustainable for healthcare systems while ensuring faster access for patients."*

While this payment model offers a promising solution, the conversation cannot remain solely within boardrooms or ministries. As **Steiners** noted, *"much of the conversation needs to take place at the societal level, involving payers and policymakers, to find sustainable pathways forward."* Germany has the resources, infrastructure, and innovation pipeline to lead in advanced therapies, but without systemic changes in reimbursement, access, and outcome measurement, the gap between innovation and implementation could grow wider.

AI & Data as the Backbone of Health

Germany is entering a critical phase in the digital transformation of its healthcare system. Data and artificial intelligence (AI) are emerging as essential tools to maintain quality and sustainability in care. Across the medTech and biopharma sectors, executives agree Germany cannot afford to delay digitalization any longer.

"In terms of trends, there's a growing emphasis on personalized medicine and precision diagnostics," said **Roberto Godoy,** Managing Director for North and Central Europe at Beckman Coulter Diagnostics. *"The integration of advanced technologies like artificial intelligence and data analytics is becoming increasingly important for enhancing patient outcomes."* But this isn't just about innovation, it's also about compliance and leadership. *"Germany's regulatory environment is influential, often setting standards that impact the broader European Union. This requires us to be proactive in compliance and quality assurance, ensuring our products not only meet but exceed regulatory expectations."*

One of the biggest promises of AI lies in making sense of the overwhelming complexity of biological and clinical data. As **Dr. Daniel Steiners** of Roche put it, *"The complexity of our research is enormous, with thousands of cell types, 20,000 genes, and countless combinations. It is impossible to process all of this in a lab without computing power."* Roche is tackling this challenge through partnerships like the one with NVIDIA, bringing advanced computing into biomedical innovation. **Steiners** envisions a future where anonymized health data becomes available for analysis through large language models, saying, *"Imagine if this data were available for companies to analyze. This could lead to the generation of new hypotheses on how to approach and treat certain diseases."*

But realizing this vision in Germany requires more than computing power; it requires trust and regulatory alignment. For **Wouter Peperstraete**, General Manager DACH at Hologic, the path forward is clear but complicated. *"AI could help by identifying negative cases, allowing healthcare workers to focus on higher-risk patients,"* he explained, particularly in fields like breast cancer screening. However, he cautioned that legislative clarity is urgently needed. *"No AI is 100% accurate and mistakes will occur,"* he said. *"The key is ensuring these risks are minimal, comparable, or slightly better than today's standards."* Moreover, compensation models for physicians must adapt as well. *"If AI reduces the volume of slides a doctor reviews, it could impact their income. Striking a balance between AI investments, maintaining doctors' roles, and ensuring fair compensation is critical."*

"Data and digitalization are one of the untapped opportunities in Germany," said **Alexandra Bishop,** Country President for AstraZeneca Germany. She noted that currently *"less than 10% of patient data is structured in a way that makes it truly usable."* But the potential is immense: *"An analysis by McKinsey shows that more digital solutions in the healthcare system could reduce costs by 42 billion euros."* **Bishop** also emphasized the potential for digital data to support clinical trial recruitment, which would stimulate further innovation and attract global investment to Germany.

Digitalization is not just transforming R&D,*"AI already plays an important role in our commercial business,"* shared **Julia Von Gablenz,** Regional President for Europe and the Middle East at Zoetis. *"For example, in Germany, we introduced tools that assist our field reps in preparing for their day. Instead of manually gathering data, these tools use AI to give reps insights on which customers to prioritize, what products to discuss, and what opportunities to focus on."*

Moreover, *"Germany remains competitive when it comes to applying AI in production and manufacturing. This leadership is bolstered by our highly qualified workforce and the collaborative environment fostered by institutions like university hospitals, which are significant factors attracting health industry investments to Germany. Nonetheless, bureaucracy, taxation, and energy costs can impede innovation. We need structural reforms to free up companies, so they can focus more on innovation rather than red tape."* Observes **Rabea Knorr,** Head Of Department Health Industry, BDI, Germany

Across these diverse applications; clinical, production, commercial, regulatory; the message is consistent: Germany must harness its capacity for precision, compliance, and innovation to build a more data-driven healthcare system.

Germany's AI Advantage Starts with the ePA

Artificial intelligence is accelerating across healthcare, but to unlock its full potential, a robust digital infrastructure is essential. In Germany, the **electronic patient record (ePA)** marks a turning point. *"While we may not be the fastest in adopting digital technologies, we are now seeing concrete steps being taken in the right direction,"* said **Achim Hartig**, Managing Director of GTAI and Chair of the OECD IPA Network. *"One key development is the introduction of the electronic patient record, or ePA, which is an important milestone."*

The **ePA** is a centralized, secure digital file that stores a person's complete medical history, prescriptions, imaging, diagnoses, test results, and is accessible to patients and authorized providers. Patients retain control over what is shared and with whom.

What makes the ePA transformative is not just digital access, but **its role in enabling anonymized health data to be used for research and innovation**. As Hartig explained, *"The regulatory framework is evolving to allow data from electronic patient records to be combined with information from health insurance providers, enabling its use in research while still upholding Germany's strong data protection standards."*

This balance between privacy and progress positions Germany to lead in AI-driven healthcare. As **Hartig** put it, "*Whether you look at genome analysis, personalized medicine, or molecule design, the potential here is truly transformative. "AI is becoming a unifying force across domains. At this point, the scope of its applications seems limitless."*

Keep Investing in Germany

"Innovation cycles are becoming shorter, with new advancements reaching the market faster due to rapid technological progress," states Mikko Vasama, Managing Director of Philips Health Systems DACH. *"At Philips, a significant portion of our R&D investment is directed toward technology, specifically software, data, and A, because these areas are critical to the future of healthcare."* While Germany has built a great reputation as attractive investment hub, the country must evolve to remain competitive. And this does not happen in isolation. Many local stakeholders, including biotech clusters, are pushing for reforms that enhance Germany's attractiveness to global capital. *"One of our key efforts is engaging with both the federal and state governments to push for regulatory changes that make it easier to establish and finance companies,"* says **Prof. Dr. Ralf Huss, Managing** Director of BioM Biotech Cluster Development GmbH. He notes that while structures like the German GmbH make it easy for founders to launch, they're less suited to growth-stage companies looking to raise international capital or exit through public markets.

Germany's relatively weak IPO landscape is also a concern. "*The German stock exchange is hesitant to list small or nano-cap companies,*" **Huss** says, citing the success of NASDAQ, Denmark, and the Netherlands in attracting life sciences IPOs. *"We are working to change this mindset by advocating for more flexibility in Germany's financial market to encourage IPOs and attract private capital."*

A critical piece of the puzzle will be sustained investment in pharmaceutical and medTech manufacturing, especially amid global supply chain volatility.

Jan Kengelbach, CEO of Aenova Group states: "*This sector has strong long-term fundamentals but requires continuous investment, regulatory flexibility, and a pricing environment that ensures profitability. If that balance is found, Europe can secure its supply of essential medicines while still fostering innovation and growth."*

Ultimately, the opportunity for Germany is not just to retain its role as Europe's industrial backbone, but to position itself as a strategic innovation leader in healthcare, where medtech, biotech, pharma, providers and regulation should converge to deliver smarter, more equitable care.

"Scientific advancements are a force for good," says **Alexandra Bishop**, Country President at AstraZeneca Germany, who is optimistic about the sector's future. "*It's encouraging to see that the perception of pharma has begun to shift to being viewed as part of the solution for a healthier future, and a positive contributor to the economy and growth. My hope is that we continue to evolve into an even stronger location for innovation."*

Julia Von Gablenz

Zoetis

Regional President Europe And Middle East, Zoetis

EF: What are the main priorities on your agenda this year?

JG: In recent years, Zoetis has cemented its position as the global leader in animal health, and the opportunities ahead remain promising.

> "Our success is built on a strong strategic framework. Through continuous R&D investment and our differentiated portfolio, we advance progress in our key franchises, including small animals and equine, and strengthen livestock innovation."

There continues to be a vast, unmet need in veterinary medicine, such as the lack of treatment options for chronic diseases in cats and dogs, and the livestock sector demands sustainable solutions to enhance productivity. We continuously invest in innovative solutions to meet the needs of companion animals, focusing on areas like renal, cardiology, diabetes, and oncology, while also prioritizing lifecycle innovation to match the preferences and expectations of veterinarians, producers, and pet owners.

While livestock once represented the majority of our business, the small animals segment has been a growth driver for years. Today, it represents over 60% of our global revenues. We continue to see that evolution continue as pet owners are increasingly visiting veterinarians and investing in therapies that enhance their pets' lives. Our expertise in dermatology and osteoarthritis pain (OA) in dogs and cats is industry-leading. Our monoclonal antibodies in these areas have transformed the quality of life for pets and their owners, and we are committed to further expansion.

However, the livestock sector remains vital due to its role in food production for the global population. We are dedicated to continued investment in this area and to supporting farmers through a comprehensive approach focusing on disease prediction, prevention, diagnosis, and treatment.

EF: What is the role of diagnostics for Zoetis?

Although currently a smaller segment, Diagnostics has significant potential and is another area for future growth. AI is transforming diagnostics, treatment plans, and patient monitoring. These technologies enable faster and more accurate disease detection, personalized treatment plans, and predictive analytics for better health outcomes. A few years ago, we launched an AI-powered diagnostic tool called Vetscan Imagyst. It allows veterinarians to scan samples in their clinics, which are then sent to the cloud for an AI-based diagnosis. This tool was the first of its kind and is an excellent example of how AI is transforming veterinary care.

EF: What is Germany's strategic importance to Zoetis globally?

JG: Germany is the fifth-largest animal health market in the world. Over the past five years, the German market has shown steady, mid-single-digit growth, and Zoetis has consistently performed strongly in this region. We estimate the German animal health market to be worth around $1 billion, and Zoetis has consistently outperformed the market over the last five to ten years. Our innovations, such as monoclonal antibodies, have driven our success, but other factors have also played a role. Germany is a key market for us, and our strong performance highlights the important role we play in it. Notably, we achieved market leadership in Germany in early 2023, a milestone we are very proud of.

EF: How can the new, recently announced commercial structure at Zoetis drive synergies across markets?

JG: Our new structure is designed to focus on the growth of both our business and reflects our commitment to effectively addressing local needs and priorities in a highly dynamic external environment. I am thrilled about taking on this new role as Regional President for Europe and the Middle East.

Europe is a mature and important region – the second-largest animal health region in the world after the U.S. and plays a crucial role for Zoetis. The Middle East, however, presents a different picture. While the pet care segment is a major revenue driver in Europe, the Middle East emphasizes production of animals like poultry and cattle, presenting significant opportunities for us in that region.

Despite some differences between these regions, there are also many similarities, especially regarding customer needs and standards of veterinary medicine. Both the European markets and the markets in the Middle East are incredibly dynamic. This makes it a great opportunity for Zoetis to build on our strengths and elevate our role across this region's animal health sector.

EF: How are you using digital tools and data to improve operations in Germany and the region?

In Germany, we launched our e-commerce channel about two and a half years ago, allowing veterinarians to order directly from us 24/7 through our online shop. This has quickly become our most important sales channel, showing tremendous growth. Additionally, we have been expanding digital communication with both customers and pet owners. For example, we run direct-to-consumer education campaigns to inform pet owners about diseases, leveraging digital platforms to spread awareness. For veterinarians, while face-to-face interaction with our reps remains their preferred communication channel, we have been supplementing this with digital tools to enhance education, customer service, and engagement.

EF: What steps are you taking with AI, and how do you see it shaping future operations?

JG: First of all, I want to emphasize that AI and data science are revolutionizing drug discovery and development. By harnessing vast amounts of clinical and non-clinical data, the industry can make faster, more precise decisions in creating new medicines and vaccines. This approach may help reduce the time from discovery to market.

Beyond R&D, AI already plays an important role in our commercial business. For example, in Germany, we introduced tools that assist our field reps in preparing for their day. Instead of manually gathering data, these tools use AI to give reps insights on which customers to prioritize, what products to discuss, and what opportunities to focus on. I believe we are leading the industry in this area.

EF: How are you driving the use of AI at Zoetis?

We are enhancing digital fluency among our employees, providing extensive training on digital tools and AI capabilities. We encourage our teams to integrate AI into their daily work in various ways. However, it is also important to emphasize that critical thinking is needed more than ever to evaluate the results of AI systems and ensure they are accurate. An ethical and responsible approach to AI is of crucial importance to us at Zoetis.

EF: Reflecting on your 17 years with the company, what achievements are you most proud of?

JG: I have been with Zoetis since day one and experienced the transition from Pfizer to Zoetis. Witnessing the company's growth in identity, culture, and core values has been incredible. Our senior management has excelled in bringing Zoetis to life, and I am proud to have been part of this journey, including the IPO and everything that followed.

Jan Kengelbach

Aenova Group
Chief Executive Officer

EF: What are Aenova Group's key priorities and main opportunities in Germany for 2025 amid global changes and a new government?

JK: Our strategy is fully customer-centric, keeping clients—and the patients they serve—at the heart of everything we do. As a service company, our goal is to provide the best service in Europe while investing in cutting-edge technologies that set us apart and drive innovation. This year, we are investing 120 to 130 million Euros to expand our facilities across 14 locations, seven of which are in Germany. This will increase production capacity and support new technologies, enabling us to serve customers better and improve patient care.

Key initiatives include a new aseptic center in Italy for prefilled syringes, a spray drying platform in Ireland, a hot melt extrusion platform in Germany, and a gummy production platform in Romania for over-the-counter drugs, as well as vitamins and supplements. Leveraging deep expertise across diverse dosage forms and markets, we continuously innovate and advance our technological capabilities to stay ahead in the industry.

EF: How is Aenova adapting to global competition and emerging trends like personalized medicine and cell therapies?

JK: Measuring progress can be tricky, but one way to look at it is through business growth. When I started at Aenova eight years ago, we were securing around €60–70 million in new business annually. Last year, that number jumped to €210 million, despite operating in predominantly high-cost European countries.

A key factor in staying competitive is our ability to control costs. In many of our plants, once you factor in transport risks and retesting, our conversion costs are actually lower than those of Indian competitors. That is no coincidence — it is the result of deliberate investments in automation and next-generation machinery. Take blister packaging, for example. Where 100–150 blisters per minute were once considered efficient, our latest machines now run up to 700 blisters per minute. At this scale, labor costs become far less critical, making us highly competitive.

However, cost efficiency is not enough on its own. Reliability — delivering on time and at top quality — is even more important. Not every CDMO has kept pace here. Investing in advanced technology requires financial strength and access to capital.

A few years ago, we reinvested 4–5% of our revenue; today, that's grown to 12–13%. That level of reinvestment is only possible with strong profitability and shareholders willing to support long-term growth over short-term gains. It is this strategy that allows us to stay ahead.

EF: How do you envision Aenova's long-term investments, and how will they shape operations over the next years?

JK: Everything we invest is self-funded by the business's operating profits, and if we need to make bigger investments, such as acquisitions, we can use our healthy balance sheet to do so.

> **"What differentiates us is our ability to invest strategically in new technology, often with pre-sold capacity or co-investment agreements with customers. This enables us to keep expanding in Europe, especially in high-tech, highly automated manufacturing."**

Looking at the market, big pharma companies are investing billions in manufacturing. Setting up a single aseptic production line today can cost €30 to €50 million — often an entire annual capex budget of smaller CDMOs. That limits many companies to adding one new line every few years while maintaining existing operations.

Of course, not all production makes sense to keep in Europe. For generic OTC ("over the counter") drugs like paracetamol or ibuprofen India remains the most competitive location. But for prescription and more complex medications, there is still a strong case for European production.

EF: How is Aenova integrating AI technology into its platforms, and what opportunities do you see for further innovation in the sector?

JK: Our Aenovation™ program is designed to streamline pharmaceutical development, deploying a science-based rationale selection of formulation and technology. Computational analysis and algorithms play a key role in this process. This initiative aims to bring new products and development services to the market, focusing on advanced technologies like spray drying and hot melt extrusion. Without heavily marketing these services until now, we have already attracted strong market interest — many companies need certified platforms to bring their products to market. As a result, we are now working with several new chemical entities (NCEs) that could become major commercial products.

This brings us to technology and digitization, which are central to our long-term strategy. In certain areas of production, we are using data-driven process optimisation, which enables us to exploit a significant amount of potential. The goal is simple: bring our systems to world-class standards and make Aenova the top pharmaceutical manufacturing partner in Europe. While our current systems work, we want to elevate performance and efficiency across the board.

In many manufacturing sites, more indirect employees manage paperwork and compliance than direct workers on the machines. But AI and digital tools can change that. Automated systems can now handle batch records and product quality reviews just as effectively as manual checks. We are not fully there yet, but we are laying the groundwork, ensuring data is structured properly and eliminating manual entry wherever possible.

EF: Could you elaborate on your company's sustainability strategy and its impact on environmental health?

JK: When a company reaches a billion euros in revenue, it has to take its role as a responsible corporate citizen very seriously. Ideally, that starts earlier, but with 4,000 employees and a large manufacturing footprint, it becomes essential. And that commitment has to come from leadership.

We're preparing to launch our official sustainability policy later this year, with clear targets for reducing scope 1 and 2 emissions. A key priority is switching to 100% renewable electricity, along with lowering wastewater and overall energy consumption. We've created a dedicated sustainability department that works plant by plant to set reduction goals.

But sustainability goes beyond environmental goals. It is about good governance and community engagement, too. These factors make us more attractive not just to investors, but to employees who want to work for a company that's genuinely improving.

EF: As a final message, what must happen to ensure health is seen not as a cost but as a long-term investment at the European level?

JK: The key going forward is for policymakers and investors to recognize that pharmaceutical manufacturing is not just a cost but a strategic investment in Europe's health security. This sector has strong long-term fundamentals but requires continuous investment, regulatory flexibility, and a pricing environment that ensures profitability. If that balance is found, Europe can secure its supply of essential medicines while still fostering innovation and growth.

Ulrich Hoppe

German British Chamber of Industry and Commerce, AHK UK
Director General,

EF: How do you assess the current landscape regarding bilateral relations and the investment environment, and what are the current priorities on your agenda?

UH: Since the Brexit referendum, there's been a lot of uncertainty on both sides. Businesses thrive on predictability, and that wasn't the case for years. It wasn't until Brexit officially happened, first politically on January 31st 2020, then commercially at the end of that year, that clarity emerged. So, for the past four years or so, things have settled to some extent. That initial uncertainty impacted investment, and some supply chains had to adjust. But over time, things have started to normalize. Of course, COVID-19 also played a role, which made it easy for both sides to argue their case. Brexit supporters could blame disruptions on the pandemic, while opponents pointed to Brexit. In reality, both had an impact. COVID-19 likely had the bigger short-term effect, while Brexit continues to shape things long-term.

Trade tends to be more short-term and has largely returned to pre-Brexit levels. Investment, however, is a different story; it requires stability and long-term planning, often over 5, 10, or even 15 years, depending on the industry. When Brexit finally happened, companies had to adjust to new trade barriers and administrative requirements. Logistics firms had to adapt, businesses had to navigate new regulations, and while these changes added some costs, maybe 1–2%, depending on the sector, have been manageable. The bigger challenge is that the UK's economy is heavily service-driven and networked. Businesses rely on bringing people together quickly, often across borders, which isn't as simple as adjusting paperwork. That's the real long-term shift that companies are still figuring out.

Since Brexit, the UK no longer has freedom of movement, and immigration rules have tightened. Visas are now required for many activities, and they're not issued on the spot, which has made the UK less attractive for certain things. This has distanced the UK economy somewhat, and while it's not a major short-term issue, we're seeing longer-term effects. The long-term impact is that when you're no longer part of a network, certain opportunities don't happen. From a trade perspective, Brexit negatively affected UK-EU and global trade, particularly in goods. Services trade hasn't seen much disruption, but goods trade has struggled due to customs procedures and administrative barriers. The UK was once deeply integrated into European supply chains, with certain products finalized in the UK before being exported worldwide. With added complications, some of these activities have moved elsewhere.

That said, the UK economy hasn't collapsed far from it. While Brexit is estimated to have reduced potential growth by around 4–5%, the economy has continued to expand and, in some cases, has outperformed parts of the EU, especially Germany. The EU's overall growth has been stronger due to rapid Eastern European development. Brexit has also given the UK more flexibility in shaping its trade policies. For instance, while the EU decided to impose tariffs on Chinese electric vehicles, the UK opted not to, allowing it to adjust its approach based on its interests.

> "As global dynamics shift the UK is working to position itself as a key link between the US, Europe, and Ukraine. This could enhance its political standing and create economic advantages. While Brexit has led to lost opportunities, the UK has adapted."

EF: Are there any specific other trade hurdles that could immediately impact investment in the UK?

UH: Regulatory certainty is a big issue, especially with all the geopolitical shifts. For example, it's unclear how climate regulations will evolve and whether targets will be loosened or tightened. The carbon border adjustment mechanism is another area of uncertainty. Companies prefer regulatory alignment between the UK and the EU to avoid producing under two different standards, particularly given the UK's relatively small market. Chemical regulations have also posed challenges, requiring companies to re-register substances under UK REACH. However, some progress has been made in easing regulatory burdens. A positive step has been the UK allowing most products to use the CE marking, meaning UK manufacturers can produce under EU rules. This helps UK companies access European markets and vice versa. However, this also means the UK has become a "rule taker," accepting EU standards without a say in shaping them, something Brexiteers never wanted but has happened in practice.

Customs formalities are still a big challenge, especially for food and agricultural goods that need health checks. A phytosanitary agreement could make a real difference by cutting down on border controls, but it would mean the UK either aligning with EU standards or being seen as equivalent. The catch is that this might involve the European Court of Justice, which many Brexit supporters were against. It's a tricky balance, but finding a solution could smooth trade flows.

EF: What makes the UK attractive from a research and development perspective?

UH: The UK is a global research hub, and the English language plays a big role. The country has always been open to international expertise, making it easier for top researchers worldwide to come and work there. While Germany and other European nations also have excellent universities, the UK's language advantage, strong research clusters, and size make it particularly attractive. Size matters, too; larger research clusters tend to thrive, and the UK's flexible labor market helps. Top researchers don't need heavy employment protections; they want the freedom to move where opportunities are best. This flexibility is especially valuable in sectors like pharmaceuticals and high-level financial services, where talent is highly mobile and in demand.

Another interesting area is data protection and how it impacts research. The UK takes a more practical approach than countries like Germany, where strict data rules sometimes make sharing medical information more difficult. The NHS, despite its flaws, has a massive health database that supports large-scale research. This helps with clinical studies, identifying what works, and improving healthcare efficiency. While no system is perfect, the UK's flexibility and data-driven approach offer some valuable lessons for others. This helps with clinical studies, figuring out what works, and improving healthcare efficiency. With over 100 health insurers and tight data rules in Germany, sharing information is more complicated, which can slow things down. It's worth noting that, even with its challenges, the NHS has achieved outcomes like higher life expectancy than Germany. That's something other countries might learn from. Of course, no system is perfect, but the UK's flexibility and data-driven approach offer some valuable insights.

The current government is facing a tough challenge in healthcare. On one hand, they want to reduce waiting lists, which requires investing in hospitals, doctors, and immediate resources. On the other hand, they're pushing for more preventative care and community-based services, which are cheaper in the long run but take time to show results. Given the current financial constraints, it's nearly impossible to commit to both at the same time fully, yet politically, they have promised to do so. How they navigate this trade-off will be key.

Another aspect is the role of personal responsibility in healthcare. There needs to be more honesty in the system about what the NHS can and cannot provide. A good example is cases where patients are asked to make lifestyle changes before receiving treatment. For instance, a neighbor of mine, who was significantly overweight, was told she needed to lose almost 30 kilos before qualifying for knee surgery. This situation brings up an important point: while healthcare should be accessible to all, individuals also need to take responsibility for managing their health. Striking the right balance between public support and personal responsibility could be a promising direction for the healthcare system to explore. It's about empowering people while still providing the care they need.

EF: How do you facilitate entry into the British market in terms of your value proposition?

UH: We don't just see German companies doing business in the UK. It goes both ways, with British companies expanding into Germany as well. Our role is to support them in a few key ways. First, we're often the first point of contact when businesses want to explore new markets. We help them find potential partners, agents, and opportunities. Then, when it comes to investment, we connect them with the right people for location searches and business setup. Once they're established, our network plays a big role. Whether helping UK employees understand German business culture or supporting German executives adjusting to the UK market, having a trusted group to exchange insights is invaluable. It's not about trading secrets. Beyond that, we help companies with practicalities like VAT obligations and payroll management, especially for smaller teams. This lets them focus on growing their business without getting bogged down by administrative hurdles. Many medium-sized companies want to expand in the UK but don't want to be slowed down by paperwork. We handle the back-office tasks so they can concentrate on what they do best. While we're not experts in every industry, we specialize in handling the operational side so companies can focus on what they do best.

Thank you.

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