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Germany and Europe have every reason to remain optimistic, provided we build on the strengths we already have

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As Europe seeks to strengthen its pharmaceutical resilience and Germany redefines its healthcare and industrial priorities, the decisions taken today will shape the sector's competitiveness for decades to come. Dr Kai Joachimsen, CEO of the Bundesverband der Pharmazeutischen Industrie (BPI), discusses why restoring investor confidence, fostering innovation and creating a more coherent policy framework are essential to securing Germany's position as a leading life sciences hub.

What distinguishes BPI from other pharmaceutical industry associations in Germany?

The BPI (German Pharmaceutical Industry Association) is Germany's oldest pharmaceutical industry association, founded in 1951 and celebrating its 75th anniversary in 2026. We remain the only association representing the entire pharmaceutical value chain, from research and development through manufacturing, market access, supply and the full product lifecycle. That breadth gives us a unique perspective and credibility in political discussions because we understand the different realities and interests across the industry. BPI has also played an important role at the European level. We were a founding member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) in 1978 and, after leaving in 2008, helped establish the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) to ensure that entrepreneurial and

medium-sized pharmaceutical companies continued to have a strong voice in Brussels. The vfa (Association of Research-Based Pharmaceutical Companies) also emerged from BPI in the early 1990s, and today we continue to work very closely together.

What probably differentiates us most is that we are much more than a political lobbying organisation. We see ourselves as an extension of our member companies, providing practical expertise across market access, reimbursement, regulation, pharmacovigilance and GMP. Our teams have decades of experience supporting companies through the evolution of Germany's AMNOG framework and helping them navigate an increasingly complex regulatory and reimbursement environment.

Our work also extends well beyond Berlin. We have a permanent presence in Brussels because many of the decisions shaping our industry begin at the European level, and if you miss the discussion there, it is often too late to influence it nationally. Within Germany, our partnership with the VCI (German Chemical Industry Association) gives us a strong regional presence through our federal state associations, reflecting Germany's federal structure. Together, these capabilities make BPI both a trusted advocate for the industry and a practical partner for around 260 member companies.

How does BPI reconcile the diverse interests of Germany's pharmaceutical industry?

Representing the entire pharmaceutical value chain is both our greatest strength and our greatest responsibility. The industry is not a monolithic block, and unless you understand the different realities and interests of each member company in detail, you cannot genuinely represent it. Focusing only on research-based companies or only on generics inevitably means missing part of the picture. It makes our role more demanding when it comes to developing common positions, but it also gives us credibility because policymakers know that when they speak to BPI, they are getting a balanced and comprehensive view of the industry.

That approach has defined BPI for the past 75 years. We have consistently taken a long-term perspective, often championing initiatives that might not traditionally be associated with an industry association, from clinical trials to pharmacovigilance. Sometimes representing the industry means looking beyond individual interests and contributing to the long-term development of the sector as a whole. That has earned us trust over decades and allows us to represent around 260 member companies with authority and credibility.

What are the most pressing priorities for BPI’s member companies today?

The challenges span the entire pharmaceutical value chain, but our overarching priority is ensuring that innovation reaches patients more quickly. Regulatory approvals still take longer than they should, and we are following the discussions around the GKV-Beitragssatzstabilisierungsgesetz (Statutory Health Insurance Contribution Stabilisation Act) very closely. There are encouraging elements, including the proposed removal of the AMNOG guardrails and combination therapy discounts, while preserving the special status of orphan medicines is equally important. We fought hard to protect those incentives because, without them, developing therapies for ultra-rare diseases would simply not be viable. I experienced this firsthand while leading Chiesi Germany during the launch of the first gene therapy approved in the Western world, where the entire clinical programme involved just 27 patients. In cases like these, the regulatory and reimbursement framework has to recognise the realities of developing treatments for very small patient populations.

At the same time, around 85 percent of Germany’s pharmaceutical companies are small and medium-sized enterprises, making them particularly vulnerable to excessive bureaucracy, high energy costs and an increasingly complex pricing and reimbursement framework. We have identified around 35 different cost-control mechanisms, many of which overlap and create conflicting incentives. The cumulative effect has been a gradual shift of manufacturing away from Germany, increasing dependence on imported medicines, and producing medicines, particularly generics, has become economically unsustainable. When the average reimbursement is only a few cents per patient per day, it is hardly surprising that companies choose to manufacture elsewhere.

These pressures are unfolding against the backdrop of an ageing population, years of economic stagnation and growing financial pressure on the statutory health insurance system. While those challenges undoubtedly require reform, measures such as a manufacturer rebate that is increased from 7 to 15.5 % or tenders for patent-protected medicines would weaken the incentives to invest and innovate. That is why we continue to argue that Germany needs a framework that addresses the sustainability of the healthcare system without undermining the competitiveness and innovative capacity of its pharmaceutical industry.

How do you assess the current policy direction for Germany’s pharmaceutical industry?

The most important issue, from our perspective, is consistency. The coalition agreement rightly recognised pharmaceuticals and medical technology as strategic industries with the potential to become key pillars of Germany's future economy, reflecting the country's strengths, from world-class universities and research clusters to one of the world's largest pharmaceutical markets. Developing a new medicine, however, typically takes 12 to 13 years, requires investments of EUR 2 billion to EUR 4 billion, and succeeds only after thousands of compounds have been screened. Investment decisions are therefore built on confidence that the regulatory and political framework will remain stable over the long term.

Germany undoubtedly needs reform, but reform requires difficult decisions and the willingness to make them. There is often broad agreement that the country needs to move forward, yet much less willingness when it comes to the specific measures needed to make that happen. The concern for our industry is that recent cost-containment proposals risk sending signals that run counter to the ambitions set out in the coalition agreement.

That is why recent developments are so concerning. Germany's Pharmaceutical Strategy helped restore confidence and encouraged companies such as Eli Lilly, Daiichi Sankyo and Boehringer Ingelheim to commit substantial investments. Now, however, we are seeing how quickly that confidence can be eroded as new policy proposals create uncertainty. Trust is fundamental to long-term investment. It takes years to build, yet it can disappear almost overnight, and that is something policymakers need to handle with great care.

What needs to change to secure the long-term sustainability of Germany's healthcare system?

One of the biggest challenges is that pharmaceuticals are still too often viewed primarily as a cost rather than as a driver of health and economic value. Yet manufacturers account for only a relatively small share of statutory health insurance expenditure, meaning that even substantial reductions in pharmaceutical spending would do little to resolve the system's structural financing challenges while potentially restricting access to innovation. At the same time, the life sciences sector supports around 1.2 million highly skilled jobs and makes a significant contribution to Germany's economy, a perspective that deserves much greater recognition.

As a physician, I also believe the healthcare system needs to become much better at organising care around patients rather than processes. Too often, patients navigate the system without effective coordination, while outpatient and inpatient care remain insufficiently connected.

Incentives continue to reward the volume of interventions rather than outcomes, and digitalisation remains well below its potential. Although the electronic patient record (ePA) is an important step forward, it still functions largely as a repository of PDF documents rather than structured, interoperable health data.

These are precisely the issues we have sought to address through the reform initiative launched by BPI in the summer of 2024, which brought together around 30 stakeholders from across the healthcare system, including hospitals, physicians, statutory and private health insurers. Our recommendations focus on accelerating patient access to innovation, improving digitalisation, strengthening prevention and creating a healthcare system that rewards outcomes rather than the volume of interventions. Fundamentally, we do not believe Germany has a funding problem as much as a structural problem in the way resources are allocated and incentives are designed. As Seneca observed, *“If one does not know to which port one is sailing, no wind is favourable.”* The first step must therefore be to define what the healthcare system should achieve and then determine the most effective way of getting there.

Some of the measures currently under discussion may well be justified, but others, including the more than doubled manufacturer rebate, risk undermining innovation without addressing the underlying causes of the system’s financial pressures. Better financing of costs currently borne by the statutory health insurance system, greater investment in prevention and digitalisation, and a pricing framework that preserves a viable manufacturing base would all contribute more to long-term resilience. In our view, structural reform, rather than incremental cost containment, is what will ultimately deliver a more sustainable healthcare system.

What more needs to be done to strengthen Europe’s pharmaceutical resilience and supply security?

The Critical Medicines Act is an important step in the right direction because it reflects a growing recognition that Europe needs to become less dependent on external suppliers for essential medicines. The COVID-19 pandemic exposed those vulnerabilities, while recent geopolitical developments have reinforced the importance of strengthening Europe’s resilience. Today, the continent has very limited large-scale, vertically integrated manufacturing capacity for critical medicines such as antibiotics. As Professor Ulrike Holzgrabe of the University of Würzburg has pointed out, Europe could face serious difficulties if key suppliers were simply to stop exporting. For a region of 450 million people, ensuring the secure supply of strategically important medicines

is therefore not just an industrial ambition but a matter of healthcare security.

The challenge now is to translate that recognition into concrete action. The overall direction has been set, but Europe now needs to identify which medicines should be produced domestically, support manufacturing projects and create the conditions for companies to invest. The Critical Medicines Act cannot remain a paper exercise. At the same time, different policy initiatives need to reinforce rather than undermine one another. We fully support the objectives of the revised Urban Wastewater Treatment Directive and share the ambition of protecting the environment, but the current financing model risks making pharmaceutical manufacturing in Europe less attractive while overlooking the fact that medicines are used because they are medically necessary, not by consumer choice. Cleaner water is a shared objective, but the way we finance it must also safeguard the long-term sustainability of pharmaceutical production in Europe.

That is why policy coherence has become so important. We have appealed directly to European Commission President Ursula von der Leyen to ensure that the life sciences agenda is aligned across different policy areas. Europe cannot strengthen pharmaceutical resilience through the Critical Medicines Act while simultaneously introducing measures that make manufacturing less competitive. We see a similar contradiction in Germany, where pharmaceuticals are recognised as a strategic industry while even higher manufacturers rebates and rebate contracts for patent-protected medicines point in the opposite direction. Companies making investment decisions over decades need clear, predictable and consistent policy signals, and maintaining that trust is ultimately one of Europe’s greatest competitive advantages.

Looking ahead, what gives you the greatest confidence in the future of Germany’s pharmaceutical industry?

What continues to motivate me is the privilege of working in an industry whose purpose is to improve and save lives. As a physician, I cared for patients who today would have had access to treatments that simply did not exist at the time. Whether you look at hepatitis C, HIV or many forms of cancer, the progress medicine has made over the past decades has been extraordinary, and seeing those advances transform patients’ lives remains a constant source of motivation. As the saying often attributed to Arthur Schopenhauer goes, *“Health is not everything, but without health, everything is nothing.”* As long as there is a need for better health, there will always be a need for scientific innovation, and contributing to that mission is what continues to inspire me every day.

I am equally convinced that Germany and Europe have every reason to remain optimistic, provided we build on the strengths we already have. We benefit from outstanding universities, excellent researchers, strong hospitals and a remarkable scientific tradition, but we need an ecosystem that allows those strengths to translate into innovation rather than being constrained by unnecessary regulation. The global landscape has changed, and Europe can no longer assume that others will innovate while we regulate. If we succeed in bringing together academia, healthcare and industry within a stable and predictable policy framework, we will not only improve patients' lives but also strengthen productivity, create highly skilled jobs and reinforce Europe's long-term competitiveness. I firmly believe that strengthening our life sciences sector is one of Germany's greatest opportunities—not only to improve health, but also to drive economic growth.

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