Stephan Eder â?? President, Medicines for Europe

> Success is not just about cost efficiency; it is about ensuring our sector is seen as a strategic partner in healthcare

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European pharma is at a turning point, with rising cost pressures, regulatory shifts, and supply chain vulnerabilities reshaping the industry. As the new president of Medicines for Europe, STADAâ??s Stephan Eder is now at the forefront of driving the change that Europe needs. In this new role as head of the leading EU-level lobby group for the generics, biosimilars, and value-added medicines industries, Eder argues that long-term sustainability requires moving beyond price-driven policies to recognize the sectorâ??s broader role in innovation, resilience, and patient access.

What led you to assume the presidency of Medicines for Europe, and what are your key priorities in this role?

Stepping into this role is both a responsibility and an opportunity to drive policies that safeguard patient access to essential medicines while reinforcing Europeâ??s pharmaceutical industry. Representing Stada, I see this position as an extension of our broader obligation to collaborate with industry leaders in shaping a more sustainable and resilient healthcare system. The challenges we faceâ??ranging from supply security to evolving regulatory frameworksâ??require a unified approach to ensure that patients continue to receive high-quality, affordable medicines without disruption.

Our priorities focus on three key areas. First, we must strengthen long-term, sustainable access to medicines, including generics, biosimilars, and value-added treatments. Generic medicines already

account for seven out of ten prescriptions in Europe, and biosimilars have significantly improved access to biologic therapies, allowing earlier intervention for serious diseases and enhancing patient outcomes. Ensuring that policy frameworks fully recognize the critical role these medicines play in healthcare systems is essential for their continued availability.

Second, we need to reinforce Europeâ??s role as a global pharmaceutical manufacturing hub. The off-patent medicines sector comprises around 400 manufacturers, directly employing 200,000 people and supporting extensive supply chains. A strong, coordinated EU industrial policyâ??one that includes both member states and candidate countriesâ??is vital to securing Europeâ??s pharmaceutical sovereignty, stabilizing supply chains, and bolstering production capabilities in key areas such as active pharmaceutical ingredients (APIs), biosimilars, and generics.

Finally, advancing a strong environmental, social, and governance (ESG) agenda remains a priority. Medicines for Europe is committed to balancing patient access with sustainability, ensuring that regulatory frameworks support long-term resilience while addressing environmental considerations. Striking this balance will be key to maintaining a competitive, responsible, and future-proof pharmaceutical industry. By focusing on these priorities, we aim to drive meaningful progress that benefits patients while strengthening Europeâ??s position as a leader in healthcare innovation.

How should Europeâ??s pharmaceutical legislation evolve to secure long-term sustainable access to medicines?

A well-calibrated regulatory framework is essential to ensuring that medicines remain accessible, affordable, and sustainable across Europe. As the revision of EU pharmaceutical legislation progresses, key improvements are needed to eliminate inefficiencies, harmonize market entry conditions, and support a more flexible and responsive supply chain.

One of the most pressing issues is the harmonization of the Bolar Exemption Clause, which allows manufacturers to complete regulatory approvals, pricing negotiations, and reimbursement procedures before a drugâ??s exclusivity period expires. Currently, discrepancies in how this exemption is applied across EU member states create inconsistencies, leading to delays in market entry. A uniform approach is essential to ensuring that once a patent or regulatory exclusivity ends, generic and biosimilar alternatives can enter the market without delay, immediately expanding patient access.

Another important step would be the adoption of an Electronic Patient Information Leaflet (ePIL). Under current regulations, medicines must be distributed with printed leaflets in the official language of each country, complicating cross-border movement and creating inefficiencies in supply chains. A digital leaflet, accessible via a QR code, would allow patients to access information in their preferred language, select larger fonts for readability, and obtain simplified versions for better comprehension. Beyond improving patient experience, an ePIL would enable medicines to be redistributed across markets without the need for significant physical packaging modifications, reducing supply disruptions and strengthening access. Despite strong public and industry support, EU regulations still mandate printed leaflets, an outdated requirement that must be reconsidered.

Finally, market exclusivity periods must strike the right balance between rewarding innovation and ensuring timely competition. The European Commissionâ??s proposal to cap regulatory data protection at 11 years provides a reasonable framework, maintaining incentives for pharmaceutical innovation while preventing prolonged monopolies that delay access to affordable alternatives. Extending exclusivity periods beyond this threshold would undermine competition and restrict cost-effective treatments for patients.

By streamlining regulatory pathways, modernizing patient information practices, and maintaining a balanced exclusivity framework, Europe can create a pharmaceutical ecosystem that fosters both innovation and accessibility, ensuring that medicines remain available, affordable, and sustainable for the long term.

How can Europe ensure sustainable pricing for Off-Patent medicines while preserving competition and access?

The off-patent pharmaceutical industry plays an essential role in expanding patient access and reducing healthcare costs by introducing competition once exclusivity periods expire. However, the relentless downward pressure on prices, compounded by rigid procurement policies, is a challenge for the economic viability of especially older, long-established generic medicines, thus posing a risk for patient access to such medicines . In many European markets, manufacturers face strict pricing regulations that prevent adjustments, even as production costs rise. This has led to companies withdrawing medicines or exiting certain markets entirely, reducing supplier diversity and contributing to shortages.

To safeguard access while maintaining economic viability, Europe must transition from a price-driven procurement model to a value-based approach that considers long-term sustainability. While cost savings have been substantialâ??biosimilars alone generated â?¬10 billion in savings in 2023â??an excessive focus on price is undermining supply stability and consequently access. A more balanced system should incorporate Most Economically Advantageous Tender (MEAT) criteria, which evaluate not only price but also supply chain resilience, environmental impact, and supplier diversity. Moving away from a winner-takes-all model, which concentrates supply in the hands of a single company, would strengthen competition and prevent supply disruptions.

This approach is a core pillar of the Critical Medicines Alliance, which is shaping the forthcoming Critical Medicines Act to secure the long-term availability of essential medicines. Nordic countries have already adopted more advanced procurement frameworks that integrate sustainability criteria, and broader implementation across Europe would help preserve a plurality of suppliers, mitigate shortages, and ensure a resilient pharmaceutical marketâ??while still delivering cost efficiencies to healthcare systems.

What progress has been made on the Critical Medicines Act, and why is it essential for Europeâ??s pharmaceutical supply chain?

The Critical Medicines Act is progressing swiftly, with the European Commission aiming to present a legislative proposal by March 11, within the first 100 days of the new mandate. Led by the Critical Medicines Alliance, a coalition of industry representatives, NGOs, and EU member states, this initiative seeks to strengthen Europeâ??s pharmaceutical sovereignty. Adrian van den Hoven, Director General of Medicines for Europe, is co-chairing one of the working groups shaping its development.

The proposal is centered around three strategic priorities. The first is boosting pharmaceutical manufacturing within Europe, i.e., the European Union and candidate countries. While the region remains a key production hub, the industryâ??s expansion has to a significant degree shifted to Asia over the past 15 years. And I would like to emphasize that it is not about getting everything back to Europe, that would be misguided and practically not possible. As an industry, we advocate partnerships across the globe in the production of medicines. Thus, it is about striking a balance and

having robust and diverse supply chains both in Europe and outside of Europe. Therefore, the act aims to incentivize investment in European-based manufacturing, supporting both the expansion of existing sites and the development of new facilities. However, EU state aid regulations limit direct financial support, making private-sector funding essential. Given Europeâ??s higher regulatory and environmental costs, investment in advanced technologies, digitalization, and sustainable production processes will be critical to ensuring competitiveness.

The second priority is reforming procurement practices to improve supply chain resilience. Currently, many generic medicine tenders rely on a lowest-price, single-winner system, which, while cost-effective, increases the risk of shortages if the sole supplier encounters production challenges. The act proposes a transition to multi-supplier contracts, ensuring a more diversified and stable supply. Additionally, supply chain resilience criteria would be introduced, giving preference to manufacturers with robust production capabilities. While procurement remains a national responsibility, establishing harmonized guidelines across the EU will be crucial for long-term sustainability.

The third and most complex issue is national stockpiling policies. Countries such as France and Germany have imposed extensive stockpiling requirements, with Germany alone mandating a six-month reserve, equivalent to the annual consumption of ten smaller nations in the vicinity of Germany. If more large economies implement similar policies, it could destabilize supply chains for smaller countries. Medicines for Europe, alongside several smaller EU states, is advocating for a more balanced approach and making it, also from a regulatory perspective, easier for companies to redistribute medicines in response to shortages rather than having reserves locked within individual national borders.

By reinforcing manufacturing, optimizing procurement, and ensuring fair shortage prevention practices, the Critical Medicines Act aims to secure a more resilient, competitive, and sustainable pharmaceutical ecosystem, ensuring reliable access to essential medicines across Europe.

How have recent global crises redefined Europeâ??s pharmaceutical strategy?

While the COVID-19 pandemic was a significant catalyst for reform, the push for stronger pharmaceutical policies in Europe is the result of multiple converging crises that have exposed deep vulnerabilities in the supply chain. Beyond the pandemic, rising inflation, geopolitical instability, and post-pandemic medicine shortages have underscored the urgency of a more resilient and strategic approach to pharmaceutical security.

The pandemic made it clear that generic medicines are indispensable, particularly in the early stages when hospitals faced an overwhelming surge in demand. Countries scrambled to secure essential drugs, revealing the risks of fragmented supply chains and excessive reliance on external manufacturing. This was further reinforced by the conflict in Ukraine, which required urgent coordination to deliver over 1,200 truckloads of medicines under challenging conditions. The challenges emphasized the need for greater supply chain agility and a stronger European pharmaceutical infrastructure.

Another critical turning point was the severe post-pandemic antibiotic shortages, which were not only due to API supply issues but also delays in securing excipients, packaging materials, and other critical components. This exposed the risks of procurement models that prioritize cost above supply chain security, reinforcing the need for sustainability and resilience in pharmaceutical production. While these crises accelerated reforms, the weaknesses they revealed had long existed. The Critical Medicines Act and other policy measures now being developed reflect a broader shift toward pharmaceutical sovereignty, ensuring that Europe is better equipped to maintain stable access to

essential medicines, regardless of future disruptions.

How can Europe turn stringent environmental regulations into a competitive advantage while safeguarding medicine access?

ESG principles are at the core of the pharmaceutical industry, with expanding access to medicines itself being a key ESG objective. The industry is committed to sustainable manufacturing while ensuring the continued affordability of essential treatments. However, balancing ambitious environmental policies with pharmaceutical competitiveness and long-term medicine access remains a complex challenge.

Some European countries, particularly in the Nordic region, have already integrated environmental sustainability criteria into pharmaceutical procurement, emphasizing supply chain resilience, security of supply, and sustainable production alongside pricing considerations. This approach aligns with the broader objectives of the Critical Medicines Act, which seeks to establish more sustainable procurement frameworks across the EU.

Yet, while strict environmental regulations can drive industry innovation, they must be carefully structured to avoid unintended consequences. The Urban Wastewater Treatment Directive is a prime example. This regulation proposes shifting the costs of quaternary water treatment onto the pharmaceutical and cosmetics industries, even though the issue at hand is medicine residues from patient consumption, not industrial emissions. What I would like to clarify: It is not about factory waste, which the pharmaceutical sector already manages through strict environmental standards. This policy disproportionately impacts high-volume, essential medicines such as cardiovascular and diabetes treatments, making them less economically viable. This could lead to market withdrawals, increasing shortages rather than addressing them. In short, it is a tax on medicine consumption for patients who are prescribed these medicines by their doctors to treat an illness, and some medicines might simply disappear from the market.

For Europe to remain competitive while upholding both sustainability and access to medicines, environmental policies must be holistic and aligned with broader healthcare priorities. A regulatory framework that balances innovation, supply resilience, and environmental responsibility will ensure that pharmaceutical production remains sustainable without compromising patient care.

How are geopolitical shifts reshaping Europeâ??s pharmaceutical industry and global partnerships?

The pharmaceutical industry operates within a deeply interconnected global framework, relying on diverse supply chains, international manufacturing, and strategic partnerships. Recent geopolitical challengesâ??including COVID-19, the war in Ukraine, and growing protectionist policiesâ??have intensified discussions around supply chain security. However, rather than advocating for complete pharmaceutical self-sufficiency, industry leaders emphasize the need for a balanced approach that reinforces European manufacturing while maintaining strong global cooperation.

The Critical Medicines Act and Critical Medicines Alliance reflect this shift, prioritizing investment in domestic production, particularly for generics and biosimilars, while recognizing that Europe cannot and should not operate in isolation. Expanding manufacturing facilities within the EU and in candidate countries like Serbia is a strategic step, yet collaboration with key partners in India, China, Vietnam, and the US remains essential for securing APIs, raw materials, and finished products.

At the same time, Medicines for Europe remains committed to global solidarity, resisting protectionist pressures that threaten medicine access. During COVID-19, when certain countries sought to restrict exports, the industry opposed such measures, reinforcing the principle that pharmaceutical supply chains must prioritize patient needs over isolationist policies. This international commitment is also reflected in industry leadership. Lucas Sigman, CEO of Insud Pharma, now chairs the International Generic and Biosimilar Medicines Association while continuing to serve on Medicines for Europeâ??s executive board, demonstrating that European pharmaceutical resilience and global collaboration are not mutually exclusive but fundamentally interconnected. In an evolving geopolitical landscape, the focus remains clear: building a more diversified, resilient supply chain that integrates European production strength with global partnerships, ensuring long-term stability and uninterrupted access to essential medicines.

What legacy do you hope to leave as President of Medicines for Europe by 2027?

A meaningful legacy is not built on individual achievements but on what we, as an industry, accomplish together. Our ambition is to elevate the discussion beyond cost considerations and ensure that the pharmaceutical sector is recognized for the value it brings in expanding patient access, driving innovation, and strengthening healthcare systems. While affordability remains fundamental, it must not overshadow the critical role our industry plays in long-term healthcare sustainability and treatment advancements. An important role in this context is with value-added medicines, which enhance existing treatments through new indications, improved formulations, or combination therapies. In areas like cardiovascular care, combination treatments improve adherence and significantly enhance patient outcomes, demonstrating that pharmaceutical innovation is not only about new drug development but also about maximizing the impact of established therapies.

By 2027, I want our industry to be seen not just as a cost-saving sector but as an essential partner in healthcareâ??one that policymakers and patients can rely on to ensure sustainable access, advance treatment effectiveness, and drive long-term medical progress across Europe.

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