Without competition, the patient pays the price



The importance for patients of generic and biosimilar competition in the medicines market

Medaxes
Association for accessible medicines

Medaxes is the Belgian umbrella organisation for pharmaceutical companies that wish to contribute to healthcare accessible to all and strives for the optimal use of essential medicines, including generic and biosimilar medicines.

Medaxes is the centre of expertise for essential medicines and provides high-quality solutions for a policy focused on cost-effective, well-regulated and sustainable healthcare.

As a key organisation, Medaxes strives for dialogue and partnership with other stakeholders in the healthcare sector.



Without competition, the patient pays the price

The importance for patients of generic and biosimilar competition in the medicines market

Competition in the medicines market plays a crucial role in ensuring affordable, accessible and high-quality care for Belgian patients.

Due to the specific characteristics of medicines, such as high research and development costs, patent rights, evergreening and strong regulation, competition within the healthcare system does not arise spontaneously. It is precisely for this reason that actively monitoring and stimulating competition is of great systemic importance from the patient's perspective. In practice, competition in the medicines market is primarily driven by the availability of generic and biosimilar medicines, which, once the patent has expired, provide equivalent alternatives for patients and healthcare providers.

Competition in the medicines market is of fundamental importance to patients, as it leads to lower prices, better accessibility, higher quality, greater freedom of choice and greater security of supply. These benefits do not come about automatically, but require active policy choices that facilitate and support competition. Effective competition policy and appropriate regulation are necessary to ensure that patients' interests remain central to the medicines market.

The generic medicines industry is central to public healthcare

Our sector supplies essential medicines on which patients, healthcare providers and healthcare systems rely for the treatment of most acute and chronic conditions, ranging from cardiovascular diseases and diabetes to even cancer.

Generic medicines have radically transformed healthcare in our country by significantly increasing patients' access to medicines at a time of rising demand for care and limited financial resources.

Over the past ten years, generic medicines have increased access to medicines in Europe by more than 100% across seven key therapeutic areas, without increasing overall treatment costs.

Thanks to this development, millions of Belgian patients have benefited from improved access to therapies of the highest quality standard.



The biosimilar medicines industry is driving quality in public healthcare

Biosimilars were developed in Europe twenty years ago to address the urgent need for better access to biopharmaceutical medicines in Europe. Studies showed that there was inequality in access to biological medicines for the treatment of conditions such as rheumatoid arthritis, as lower-income countries in Europe could not afford such therapies.

Even within high-income countries, only 10–14% of patients with rheumatoid arthritis received treatment with biologics. Significant benefits await patients who, thanks to the arrival of biosimilar medicines, gain access to treatment with biologics, in both low- and high-income countries within the EU.

Thanks to advanced new technologies, our sector achieved a world first with the first approved biosimilar medicine in 2006. Since then, our industry has continued to invest significantly in new innovations, resulting in a sharp increase in the total number of biosimilars available on the European market today. The use of biosimilars in our country remains suboptimal to this day, meaning that their therapeutic and budgetary potential is not being fully utilised.

"Thanks to biosimilars, I can now administer my own rheumatism treatment at home"

Guillaume was diagnosed with rheumatoid arthritis at a young age. Conventional treatments had a severe negative impact on his quality of life. That changed dramatically with the introduction of the biologic medicine infliximab.

"Thanks to infliximab, I got my life back. I can once again actively participate in social life with my peers. The extreme fatigue I experienced from the standard treatments used to make that impossible."

With the arrival of biosimilars, treatment became even more accessible for Guillaume. The medicine was further developed for home use, which made a huge difference to his daily life.

"The subcutaneous form of infliximab, which is available as a biosimilar, means I no longer have to go to the day hospital to get my medication. I can now treat myself at home. That gives me the feeling that I really belong again. At my age, that is hugely important, and thanks to biosimilars, it is once again within reach."



"Healthcare must remain accessible to everyone, not just today but tomorrow as well. This is only possible if all stakeholders work together on sustainable future models that offer viable prospects for everyone involved."

Nele D'Haeze, Director of Pharmaceutical and Governmental Affairs - Medaxes



Competition makes a substantial contribution to cost control

The impact on the costs associated with the reimbursement of medicines

When multiple suppliers are active in the market, particularly following the expiry of patents and the entry of generic and biosimilar medicines, strong price pressure arises. After all, legal provisions ensure that generic or biosimilar competition leads to massive price reductions compared to the price level of branded medicines with a monopoly. The prices of the original branded medicines are also legally reduced once the generic or biosimilar is commercialised.

This creates a level playing field in the market, allowing competition to function effectively. The sooner generic and biosimilar medicines are effectively admitted to the market, the sooner these budgetary and price-related benefits will reach patients, both directly and indirectly.
After all, lower medicine prices resulting from competition not only reduce the direct financial burden on patients by affecting the patient contribution, but also help to control collective healthcare expenditure, which indirectly increases the affordability of the healthcare system for the patient.

It is therefore of the utmost importance that this competition is allowed onto the market swiftly and that anti-competitive elements are removed from pricing regulations and the reimbursement system. Simpler, more efficient and more predictable procedures for authorisation, pricing and reimbursement can accelerate market access, thereby enabling patients to benefit more quickly from affordable alternatives. This also enhances Belgium's attractiveness as a market and reduces the risk of our country being regarded as a non-priority market for launches at European level.

The impact on the price of medicines that are not reimbursed or are available over the counter in pharmacies

In Belgium, the government imposes price reductions on medicines that introduce competition but does not require this of the original branded medicine that previously held a monopoly. This can be described as systemic discrimination. As a result, new generics have less financial scope to roll out commercial activities, meaning that patients are often unaware that cheaper alternatives exist.

Greater transparency and visibility of available alternatives are essential to enable patients to make conscious and informed choices, in consultation with their healthcare provider. Examples from other countries clearly demonstrate that the absence of mandatory price reductions for non-reimbursable (generic) medicines leads to more available alternatives and stronger price dynamics.

Any price reduction achieved through competition benefits the patient in full when there is no reimbursement. In Belgium, clear gains can be made at this level, which will expand the range of options available and enable the patient (naturally in consultation with their healthcare provider) to make a more informed choice of the most cost-effective treatment option.

"The savings achieved by the RIZIV thanks to generics and biosimilars amount to more than 4 billion euros annually. This money benefits patients through the reimbursement of new, innovative medicines and better access to the healthcare system in general."

Wim Vervaet, Director of Strategy & Policy, Medaxes



Competition promotes access to medicines

Monopolies and limited access to medicines

High prices and monopolistic market power can make certain medicines less accessible to patients, for example due to limited reimbursement. The use of certain, very expensive medicines is only reimbursed for limited groups of patients who are expected to show the greatest health benefits. Other patients who could also benefit from these medicines are often excluded because it is considered that the cost is disproportionate to the expected health benefits.

Competition removes budgetary barriers to treatment

Competition lowers these (artificial, budgetary) barriers to treatment and thereby increases the likelihood that patients will have timely and consistent access to treatments that optimally benefit their health. Accessibility is determined not only by price, but also by timing and scale: the faster and more widely a treatment becomes available, the greater the health benefit for the patient.

Stimulating competition is the lifeblood of an affordable healthcare system

Systematically re-evaluating the societal benefits of treatment at the moment market competition can begin can, through expanded reimbursement, have an enormous positive impact on the health of large patient groups.

Competition thereby creates a new decision-making moment: treatments that were considered ‘too expensive’ before the patent expired can subsequently be deployed more widely in a socially responsible manner.

It is therefore of the utmost importance that this competition is allowed onto the market swiftly and that anti-competitive elements are removed from pricing regulations and the reimbursement system.

Simpler, more efficient and more predictable procedures for authorisation, pricing and reimbursement can accelerate market access, thereby enabling patients to benefit more quickly from affordable alternatives.



“Competition creates a new decision-making moment: treatments that were considered ‘too expensive’ before the patent expired can subsequently be deployed more widely in a socially responsible manner.”

Antoon Daneels, Market Access & Business Intelligence Manager, Medaxes



Competition stimulates innovation, ease of use and adherence to treatment.

Incremental innovation benefits patients and enhances competitive dynamics

Competitive pressure drives pharmaceutical companies to develop new medicines, improved formulations and alternative delivery methods with, for example, better efficacy, fewer side effects or higher adherence.

Although patents offer temporary market exclusivity to reward innovation, competition ensures dynamic efficiency within the sector in the longer term. This results in medicines that are not only more affordable but also better tailored to patients' needs.

In addition to breakthrough innovations, competition also stimulates incremental innovation, such as more user-friendly dosage forms, simplified dosing regimens and improved stability. These optimisations contribute directly to treatment adherence and real health benefits for the patient.

Strengthening competition by targeting anti-competitive practices

A sustainable healthcare system that aims to guarantee the affordability of medicines must, on the one hand, take active measures against 'evergreening'. This is the strategy whereby pharmaceutical companies make minor adjustments to existing medicines – sometimes even without substantial therapeutic added value – solely to extend the patent and fend off competition.

This practice leads to unnecessarily high healthcare costs, without patients generally benefiting from it. Yet we often see that these types of medicines automatically become the new standard for all patients.

On the other hand, clearer and more transparent decision-making on patents and reimbursement can contribute to a fairer system in which the interests of patients and public finances are better served.

The improper use of patents delays the onset of competition and deprives patients and the government of the opportunity to achieve additional health gains within the available budget.

Governments must therefore take measures to prevent the abuse of patents and to promote competition in the pharmaceutical market. Strengthened antitrust measures can play a crucial role in promoting healthy competition in the pharmaceutical market, particularly when companies abuse their patent position to exclude competitors.

Stricter assessment of patent applications, monitoring of market practices, the imposition of transparency obligations and the implementation of tougher sanctions can stimulate competition in the pharmaceutical market.

"In addition to groundbreaking innovations, competition also stimulates incremental innovation, such as more user-friendly dosage forms, simplified dosing regimens and improved stability. These optimisations contribute directly to treatment adherence and real health benefits for the patient."

Katrien Hermans, Manager of Public Affairs and Communication, Medaxes



Competition increases healthcare providers' freedom of choice and patient-centred approach

The right choice is an effective choice

The availability of multiple therapeutic alternatives (ATC5 level) within a treatment (ATC4 and ATC3 levels) enables healthcare providers, in consultation with the patient, to choose a medicinal treatment option that best suits individual medical needs and preferences. This aligns with the broader aim of personalised care.

However, this freedom of choice does not automatically translate into benefits for the patient. Effective competition requires that generic and biosimilar medicines are actually prescribed in clinical practice.

Clear guidelines, incentives and sufficient confidence among healthcare providers and patients are crucial in this regard. Without the effective use of generics and biosimilars, competition remains a theoretical concept and the potential benefits for the patient are not realised, or only partially so.

Generic or biosimilar competition at the treatment option level (ATC5) can significantly reduce the societal cost, thereby enabling additional treatments or supplementary care within the same budget.

This can lead to significant gains in terms of effective patient care.

A better medicine should therefore not be more expensive

Furthermore, manufacturers of biosimilars and generic medicines are increasingly investing in further improvements to already cheaper treatment options, making innovation a way to stand out in a competitive market.

In that case, the improvement acts as a 'unique selling proposition', without the entire patient population being pushed back into a monopoly. It is a competitive market advantage but does not entail additional costs.

These improvements directly benefit the patient but have no negative impact on the Social Security budget.

A win-win situation, that much is certain!



"Without the effective use of generics and biosimilars, competition remains a theoretical concept and the potential benefits for the patient are not realised, or only partially so."

Antoon Daneels, Market Access & Business Intelligence Manager, Medaxes



Competition contributes to the security of supply of medicines

Generic and biosimilar medicines limit the impact of shortages

When medicines production is not dependent on a single supplier ("multi-source"), this reduces the risk of medicine shortages resulting from production problems, logistical disruptions or strategic market decisions by individual manufacturers. For patients, particularly those with chronic conditions, this continuity of treatment is essential.

Generic and biosimilar medicines form the cornerstone of a robust medicine supply that also remains affordable. This is the sector's social commitment to patients. 70% of the medicines used in Europe are generic medicines. Their extensive network of suppliers is of fundamental importance to the supply chain and the wider pharmaceutical sector.

Supply chain security has become a global priority for governments, as shortages of medicines critical to patient care are on the rise. Although the role of generic and biosimilar medicines in strengthening the pharmaceutical supply chain is increasingly recognised, their broader contributions to supply security are often overlooked.

Shortages of innovative, patented medicines with a monopoly are relatively rare, but shortages in the competitive segment operate differently from those in the patented segment. For off-patent medicines, multiple manufacturers can often adjust their stock distribution to meet demand within a country experiencing a shortage. However, in the case of more complex shortages – involving products with few suppliers, volatile demand and extremely low prices – these dynamics do not always fill the gap, which underlines the importance of a healthy competitive market environment.

9 out of 10 critical medicines are generic medicines

It is important to note that the number of competitors for a given product influences the risk of shortages. More than two-thirds of all reported shortages between January 2023 and 2024 were for medicines with a low number of suppliers (i.e. fewer than five suppliers) in Europe.

This suggests that ensuring continuity of supply requires sustainable levels of competition. Unlike protected branded medicines, generic medicines typically come from multiple sources, with different manufacturers producing the same product. This strengthens the resilience of the pharmaceutical supply chain in times of increased demand.

The EU list of critical medicines includes human medicines whose continued availability in the EU is considered a priority, in order to prevent serious harm to patients and to help healthcare systems function. 92% of the European Commission's list of critical medicines for major public health events and/or emergencies consists of generic medicines.

"Generic and biosimilar medicines form the cornerstone of a robust medicine supply that also remains affordable. This is the sector's social commitment to the patient."

Wim Vervaet, Director of Strategy & Policy, Medaxes

Once a patent has expired, generic medicines are often still the only option

The security of supply offered by generic medicines persists long after the loss of exclusivity, as generic medicines are often still the only available treatment option at that point.

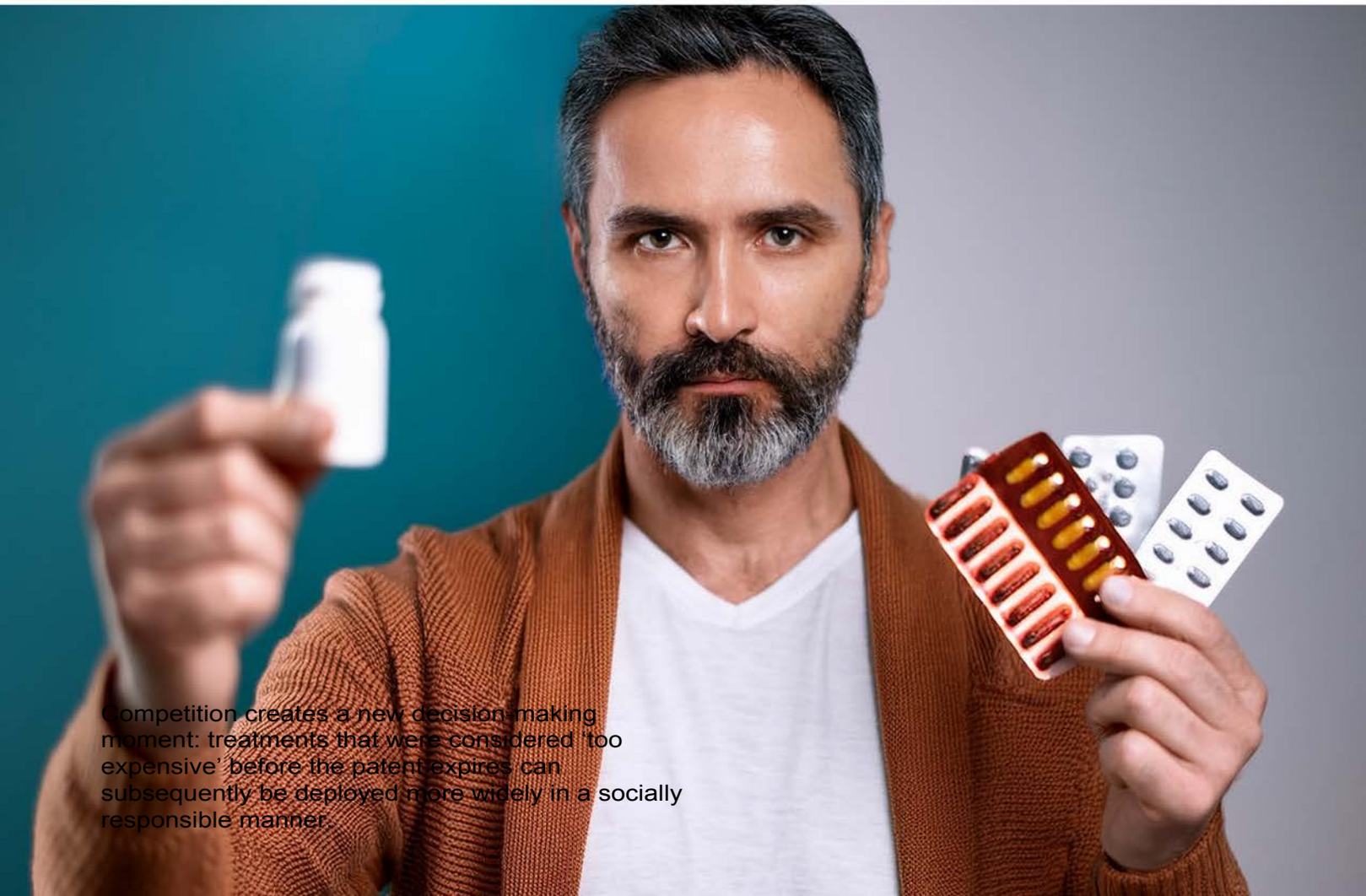
In many European markets, there is a price difference between the original patented medicine and its generic variants, meaning that the market share of the original branded medicine declines and is dynamically replaced by competing generic medicines.

Regardless of the policy measures in force in individual markets, available data suggest that generics are often the only remaining option for medicines whose patents have been expired for some time.

Typically, 40% to 50% of all off-patent products (in absolute numbers) are available exclusively as generic medicines twenty years after the loss of exclusivity.
These medicines account for 66% of the off-patent market by volume and 62% of the market by value. (SOURCE: IQVIA)

These figures demonstrate that security of supply is no accident, but the result of sufficient and sustainable competition.

However, a healthy market environment with multiple suppliers able to supply the market in an economically viable manner is a necessary condition for guaranteeing the long-term continuity of essential medicines for patients.



Competition creates a new decision-making moment: treatments that were considered 'too expensive' before the patent expires can subsequently be deployed more widely in a socially responsible manner.



Competition makes preventive medication affordable and sustainable

From a reactive to a proactive healthcare model

The availability of generic medicines plays a crucial role in promoting drug-based prevention strategies within the healthcare sector.

When the patent on an innovative medicine expires, the market is opened up to generic alternatives that offer the same therapeutic efficacy, quality and safety, but are generally available at significantly lower costs. For originator companies, these medicines often lose their commercial appeal due to the sharply reduced profit margins. For patients and the wider healthcare system, however, this price reduction represents a substantial improvement in the accessibility of essential pharmacotherapeutic interventions.

This price reduction has direct implications for preventive care. Generic medicines make it financially feasible to use medication on a larger scale for preventive purposes, for example to prevent cardiovascular diseases, osteoporosis or complications associated with chronic diseases. Early pharmacological interventions can limit disease progression and acute complications, potentially delaying or avoiding invasive and costly treatments or operations.

A recent study from Germany shows that by lowering the threshold for prescribing statins, treatment can be extended to a larger proportion of the population, thereby preventing more cardiovascular events and achieving significant cost savings for health insurance funds. Specifically, the findings show that in Germany, more than 41,000 cardiovascular events could be prevented annually among adults insured by health insurance funds, amounting to approximately €1.5 billion in cost savings per year.

Generics play a key role

From an economic perspective, the targeted use of generic medicines therefore promotes a shift from a reactive to a proactive healthcare model. Instead of investing in the treatment of conditions that have already manifested, resources can be used to implement prevention. This not only delivers better clinical outcomes and a higher quality of life for patients, but also contributes to sustainable cost control within the healthcare sector.

In summary, it can be said that generic medicines play a key role in the implementation of pharmacological prevention strategies. They increase access to essential therapies, lower the financial barrier for both patients and healthcare systems, and support a healthcare model that is proactive, cost-effective and focused on prevention.

“Instead of investing in the treatment of conditions that have already manifested, resources can be channelled into operationalising prevention. This not only delivers better clinical outcomes and a higher quality of life for patients, but also contributes to sustainable cost control within the healthcare system.”

Nele D’Haeze,
Director of Pharmaceutical & Governmental Affairs, Medaxes



Action-oriented policy advice

1. Accelerate market access and strengthen competition

- Simplify and harmonise procedures for the authorisation, pricing and reimbursement of medicines to ensure faster access to competitive medicines.
- Remove anti-competitive elements from regulations and reimbursement systems.

2. Reform price regulation and end discrimination against non-original medicines

- Encourage price dynamics for both branded medicines and generics and biosimilars when competitive medicines enter the market.
- Abolish discriminatory pricing mechanisms that restrict competitors' market entry and financial scope for marketing activities.

3. Increase transparency of information for healthcare providers and patients

- Increase the visibility of cheaper, therapeutically equivalent treatment alternatives for patients and healthcare providers.
- Encourage informed choices through transparent and easily accessible cost and supply information.

4. Review the reimbursement terms for medicines at the start of competition

- Implement a systematic reassessment of societal added value and cost-effectiveness when competition from generics and biosimilars begins.
- Extend reimbursement for treatments that become much more affordable due to generic and biosimilar competition.

5. Tackle evergreening and patent abuse in a targeted manner

- Tighten the assessment of applications for exemptions that could deter competition.
- Prevent slightly modified monopoly medicines from replacing medicines facing generic and biosimilar competition as the new standard of care.

6. Strengthen antitrust and market supervision

- Increase oversight of market practices and sanction the abuse of dominant (patent) positions.
- Impose transparency obligations and deterrent sanctions for anti-competitive behaviour.

7. Ensure security of supply through sufficient competition

- Encourage a minimum number of suppliers per medicine to prevent shortages.
- Promote diversification of production sources, particularly for generic and biosimilar medicines.

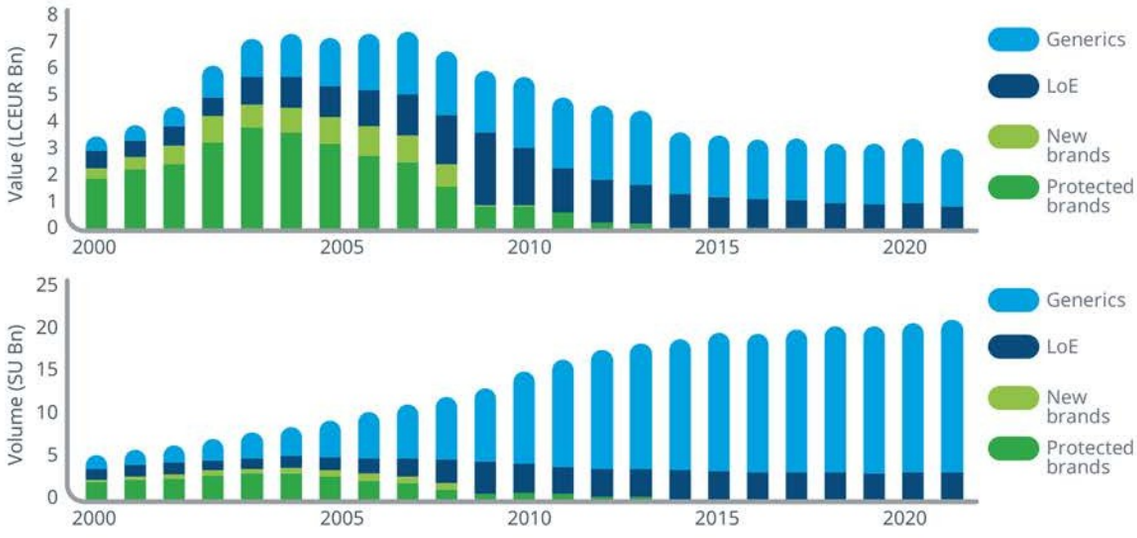
8. Use generics to develop a sustainable preventive healthcare model

- Focus more on the use of generic medicines in the active prevention of diseases with a high societal cost.
- Integrate the promotion of competition into long-term strategies for cost containment and public health.

Infographic

Self-financing growing healthcare needs through competition

Over the last 20 years, the societal cost of antacids has fallen by 60% thanks to generic competition, whilst more than twice as many patients are being treated.



SOURCE GRAPHS: IQVIA Beneath the Surface: Unravelling the True Value of Generic Medicines – European Perspectives – 2024

A policy focus on competition can ensure that market price dynamics result in self-financing of higher consumption volumes of essential medicines.

At a time when the population is growing and ageing, this could significantly ease the pressure on the healthcare system.

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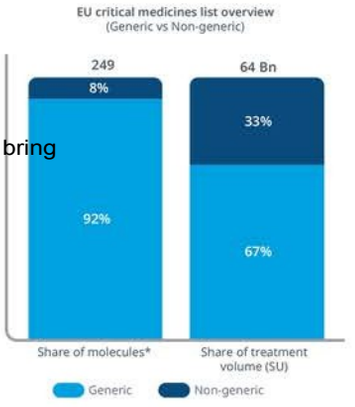
Infographic

Competition from generic medicines is the backbone of healthcare

The European list of critical medicines consists of 92% generic medicines, which together account for 67% of the volume consumed.

Investing in a favourable business environment for pharmaceutical companies that bring competition to the market is investing in the foundations of healthcare.

SOURCE GRAPHS: IQVIA Beneath the Surface: Unravelling the True Value of Generic Medicines – European Perspectives – 2024



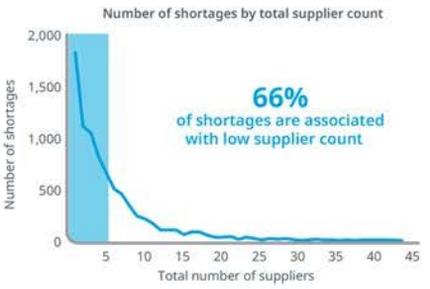
Competition reduces the risk of shortages and increases the resilience of the supply chain

Medicines with a limited number of suppliers accounted for 66% of shortages in Europe between January 2023 and January 2024.

Investing in a minimum number of suppliers for essential medicines is investing in a structurally sound market that is stable, reliable and strong.

With a healthy foundation, sustainable growth and strong domestic demand, this market model offers the best guarantee of supply security.

Furthermore, this market is attractive to investors, which in turn provides a solid foundation for further expansion and stability.



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