How inflation has disrupted generic drugs market
A perfect storm of factors has contributed to inflation in the EU reaching levels unseen in the last decade and increased prices in every area of economic activity, from shipping to raw materials and energy.

Another sector that has been severely affected and is causing a headache for EU governments is the generic drugs industry. Several cheap drugs have now disappeared from the market because they have become economically unviable to produce, directly impacting patients in need.

In Belgium, for instance, one in five off-patent medicines for sale one year ago are no longer on the market, while in Romania, over 2,000 drugs have disappeared from the market.

In this special report, EURACTIV’s network explores the reasons behind this critical situation and analyses potential solutions to get Europe out of this deadlock.

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The generics industry is urging EU and national governments to show “leadership” and take immediate action against rising inflation, which has resulted in drug shortages and has put patients in need to the test.

“We have warned the EU in July and in September that supply chains are under a lot of stress and that the risk of medicines shortages is very high,” told EURACTIV Adrian van den Hoven from Medicines for Europe, the EU generics association.

“There is a lot that we can do with the EU to get through this difficult period, but it will require some leadership,” he added.

Rising costs in energy and raw materials combined with a complex pricing regime have created an explosive mixture for the generics industry and patients.

This resulted in several cheap generic drugs being no longer economically viable to produce and, therefore, becoming unavailable in the market.

Manufacturers say they need some “breathing space” as they have gone through more than 10 years of cost-cutting policies in Europe.

“For example, in Germany, our prices were reduced by 66% since 2009, meaning an average generic medicine costs just a few euro cents per day. To adapt, manufacturers

In Belgium, for instance, one in five off patent medicines that were for sale one year ago are no longer on the market while in Romania, over 2,000 medicines have disappeared from the market.

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have consolidated supply chains, and there is very limited excess capacity,” van den Hoven said.

**Capped prices**

The industry says it’s hard to adjust prices to reflect higher costs considering that all EU countries apply capped pricing.

“This means that prices are set according to the lowest or an average of the lowest prices in the market, and then these prices cannot be increased again. So over time with inflation, these prices are permanently in decline,” van den Hoven noted.

The industry has requested a price adjustment for inflation in every EU country, but very few have so far taken any action, such as Portugal.

“In contrast, France and the UK are reducing our prices further through clawback taxes where the whole pharma industry pays for over-spending caused by a few expensive medicines,” van den Hoven said.

Drugs pricing is a national competence and the EU has in theory little room for intervention. But for the generics industry, markets could still be more sustainable “without touching national powers”.

Van den Hoven cited a Commission study on medicine tendering showing that only 24% of tenders include security of supply as a criterion and this is mainly for vaccine tenders.

“For generic medicine, tenders are only based on the lowest price. The study calls for multi-winner tenders and supply resilience criteria in tenders and the member states indicate in the study that they would need more legal guidance to do this”, he said.

**The Australian example**

In addition, the expert noted that a meeting between the industry and the EU Transparency Committee, which oversees pricing and reimbursement procedures, could be helpful in finding out how all countries can commit to the security of supply for medicines.

“If one country pays for more security of supply, but its neighbour reduces prices further, there will be no improvement in security of supply for Europe because the policies will cancel each other out.”

The expert cited as an example
Canada, who applies a "ladder policy" where prices go down when there are many generic manufacturers on the market (like in Europe), and prices increase when there are few producers on the market (unlike in Europe).

"Australia finances rolling reserves of medicines held by manufacturers to increase supply to the market. HERA is exploring this, but it would make more sense to integrate this into national pricing and reimbursement policies," he said.

The industry's proposals may seem rational to ensure medicines supply, but the equation is tough considering that member states need to poor additional money despite the benefits for patients.

Healthcare payers agree that some drugs' prices may increase but insist that no blank check should be granted.

"Increasing the prices of some generics may indeed be necessary to rebalance and boost competition. That is not to say that lower prices are the sole root cause of shortages. The problem is not new, and it is multifactorial," told EURACTIV Yannis Natsis, director of the European Social Insurance Platform (ESIP), the umbrella organisation bringing together statutory healthcare payers.

"We need to look at prescription practices too. Overall, we must realise that resources are not infinite and signing off blank checks will not resolve the problem," he commented.

**Flexibility in packaging**

In addition to declining prices, generics are also facing practical difficulties, such as shipping costs, disrupted components' deliveries, and prolonged delays for paper and cardboard, plastics and glass often needed for packaging, mainly due to the war in Ukraine.

In order to send a pack of drugs from one country to another because of a shortage, the industry often needs to re-package and re-adapt the patient information leaflet.

To avoid this extra logistical burden, the industry calls for regulatory flexibility, as was the case during the first wave of the COVID-19 pandemic.

"We want to avoid repacking the medicines in these situations to avoid wasting precious paper. We also want to replace paper leaflets with digital information because this would simplify access to information in different languages and make it much easier for our supply chains to tackle shortages," van den Hoven said.

**EU pharmaceutical legislation**

A key document expected to deal with the matter is the much-awaited EU pharmaceutical legislation revision.

An EU source told EURACTIV that generic medicine issues might be covered by the upcoming revision of the pharmaceutical legislation without elaborating further.

EURACTIV was informed that the proposal is expected to be adopted on 14 March, with the caveat that this planning is tentative.

A leaked version of the proposal seen by EURACTIV does not mention anything on generics' pricing, given its national competence nature; however, it does simplify authorisation procedures for generics and biosimilars.

Yet, an EU list of critical medicines – which may include generics – that require coordinated EU-wide action by EMA is suggested.
Price ceilings on drugs with no alternatives must be raised, Czech industry says

By Ondřej Plevák | EURACTIV.cz

According to the Czech pharmaceutical industry and state authorities, setting price caps cannot solve drug shortages as the measure could further jeopardise drug availability.

In the Czech Republic, drug shortages are not as significant as elsewhere and often do not directly affect patients. About 150 different medicines are missing from the market every month, and with some 6,500 prescription drugs available in the country, shortages represent about 2% of the market. But there is still a risk of problems.

Data from the Czech State Institute for Drug Control showed that only 11% of drug groups were affected by such shortages.

“These groups were not easily replaceable, and therefore it was necessary to look for a substitute in the form of preparing drugs from raw materials directly in the pharmacy, special import of the drug from abroad, or changing the prescription for a drug with a different drug substance,” said Filip Vrubel, executive director of the Czech Association of Pharmaceutical Companies (ČAFF).

These drugs had to be substituted because of the lack of competition, meaning that there are only a few
suitable alternatives on the market, often no more than three.

“Competitiveness has long been threatened by the state’s heavy pressure on price, without caring whether the required savings will affect the number of traded variants of medicines on the Czech market,” Vrubel argued.

“Especially for cheap, low-margin medicines, it is unlikely that other competitors will enter the market. The small Czech market, over-regulated and with price capping, attracts no one,” he added.

The decline in margins is causing pharmaceutical corporations to have second thoughts about the continued presence of some drugs on the market. This is compounded by the unprecedented rise in the cost of manufacturing and importing drugs over the past year, which often cannot be reflected in selling prices due to price caps.

According to ČAFF, dozens of types of drugs in groups where competition is insufficient and sales prices are already at the regulatory ceiling could be at risk. These are mainly some very cheap but life-saving medicines – for high blood pressure, pain, high cholesterol or antibiotics.

**Industry: the ministry is not taking us seriously**

The industry believes that although price regulation is not fundamentally wrong, it was designed for a period of economic growth and a strong market which works better for more expensive drugs.

“There is a lack of mechanisms to respond flexibly to crisis years and inflation, as we are seeing now. Above all, we lack instruments that would stimulate supply, i.e. increase the regulated price and reimbursement in groups of cheap drugs, where the number of available alternatives has fundamentally decreased,” Filip Vrubel said, summarising the pharmaceutical companies’ opinion.

The association reportedly warned the Health Ministry about the risks more than six months ago, yet the ministry has not issued any measures.

Moreover, according to the industry, the way to go would not be a lengthy change in the law but faster government regulation. “Unfortunately, we still haven’t seen a fundamental shift,” Vrubel said, adding that the ministry “does not take the industry’s arguments seriously”.

**Not across the board, but ‘one medicine at a time’**

EURACTIV.cz asked the Health Ministry why it refuses to adjust the price ceiling for medicines that, according to the ČAFF, are in danger of becoming unprofitable for manufacturers to import into the Czech market and cannot be replaced by an alternative or a foreign-language batch.

The ministry stressed that the prices of medicines in the Czech Republic do not differ significantly from those in other European countries.

The setting of maximum prices and reimbursement is based on a reference system, i.e. according to prices in other European countries, which are not protected by trade secrets.

As for raising the price ceiling, the ministry says it cannot distinguish between different categories of medicines in this respect and would have to do so for all medicines with a maximum price and reimbursement. In other words, even those drugs have high margins and do not require regulation.

“That is why we have decided to approach this on an individual basis,” the ministry’s spokesman Ondřej Jakob told EURACTIV.cz.

More specifically, if a manufacturer is considering leaving the market because it is not worth staying due to the maximum price and reimbursement set, the ministry, in cooperation with health insurance companies, could increase the price in the public interest.

The drug would then remain available to Czech patients.

“We will definitely not do this across the board, but individually for drugs where their availability would be at risk,” Jakob added.
“There is a lack of mechanisms to respond flexibly to crisis years and inflation, as we are seeing now. Above all, we lack instruments that would stimulate supply, i.e. increase the regulated price and reimbursement in groups of cheap drugs, where the number of available alternatives has fundamentally decreased.”

Filip Vrubel
Executive director of the Czech Association of Pharmaceutical Companies (ČAFF)
Leading representatives of the generic and biosimilar pharmaceutical industry in Spain have alerted authorities of the damage they are suffering due to the low prices of their drugs.

They are calling for their profitability to be guaranteed to continue saving resources for the National Health System (SNS) and, ultimately, to protect patients.

According to data from the Organisation for Economic Co-operation and Development (OECD), the selling price of medicines in Spain is around 16% lower than the European Union (EU) average. While in December 2009, the average cost per
prescription was €13.39, it has now fallen to €10.81, almost 20% less than ten years ago, according to the international organisation.

To mitigate pharmaceutical costs, the Spanish Ministry of Health has lowered the reference prices of more than 1,000 drugs, some of them included in the lists of medicines considered “essential and strategic” by the World Health Organisation (WHO) and the Spanish Agency for Medicines and Medical Products (AEMPS).

The strong impact of inflation

The minimum reference price has been set at €1.60 (previously €1.80), with some drugs priced even below the threshold, which, according to the generics and biosimilars industry, is close to the limit of profitability.

In interviews with EuroEFE, the managers of two key players in helping to guarantee the financial sustainability of the health system, generic drugs and biosimilars, warn of the risk to some drugs if a minimum profitability threshold is not maintained.

The Director General of the Spanish Generic Medicines Association (AESEG), Ángel Luis Rodríguez de la Cuerda, defends the “social usefulness” of generic medicines, thanks to which, he says, the health system coffers achieve substantial savings.

“Generic drugs produce very considerable savings for the National Health System in pharmaceutical costs of at least 40% and contribute to wider patient access to medicines,” he told EuroEFE.

However, the expert considers that, in the current complex inflationary context, among other factors, from the war in Ukraine, in order to guarantee the continuity of generics, “it is urgent to be able to raise prices somewhat”.

“Despite the fact that generics are medicines of the same quality, efficacy and safety as their brand-name counterparts and that we are endorsed by AEMPS and the European Medicines Agency, we are currently suffering from the problem of low prices,” said the head of AESEG, which represents 95% of the companies in the sector in Spain.

The generics industry in Spain, directly and indirectly, employs around 40,000 people. It has 20 manufacturing plants throughout the country, invests 27% of its profits in innovation and development, and exports 30% of its products mainly to other EU countries, according to AESEG data.

A ‘minimum threshold’ of profitability

He said the average price of generics in Spain is around €3.50, but almost 50% of all generics are priced at €1.60 or less.

“We are being hit by several external factors. Since the pandemic and for the last year with the war in Ukraine, the price of energy, transport and raw materials has skyrocketed, and all these elements have had a powerful impact on generics, which already have lower prices. In addition, the situation has been aggravated by the unstoppable rise in inflation,” he said.

Biosimilar (the equivalent of generics for branded biological drugs) share the same problems, although there are notable differences in several aspects, Encarnación Cruz, general manager of the Spanish Association of Biosimilar Medicines (Biosim), told EuroEFE, while highlighting the benefits of this type of drug.

“They were a turning point in the treatment of certain pathologies. For example, a cancer patient whose treatment possibilities had previously ended, today (with biological drugs) can see their life expectancy significantly prolonged, and in some cases even cured,” said Cruz.

However, she points out that “these are very expensive drugs, costing almost €100,000 (in some cases), and that limits their use considerably.”

On the other hand, Cruz stressed that biological and biosimilar medicines are “the future”, as 71% of all drugs approved by the European Medicines Agency (EMA) in 2021 were biological.

“Unlike generic drugs, which suffer two price decreases (after their authorisation, and then annually with the state regulatory setting of reference prices), biosimilars suffer a third decrease,” she said.

She noted that the authorisation of a biosimilar by the EMA and prior to marketing in Spain, the Interministerial Commission sets the price at which it will be financed by the National Health System.

“There is no fixed rule for determining the discount to be applied to biosimilar medicines, but the most common is that the financing price of the biosimilar is 20-30% lower than that of the original. This is the price that will be used for sale in pharmacies,” Cruz said.
In her opinion, although biosimilars have, among other objectives, to contribute to the sustainability of the NHS, it should not be forgotten that, for the industry, their production has to be minimally profitable.

“If we break the profitability threshold, they (biosimilars) may disappear from the market. For example, the pharmaceutical industry may no longer be interested in developing a biosimilar. And, in the end, the biggest problem will be for patients,” Cruz warned.

In Spain there are only 11 production centres for biological drugs, and of these, only two manufacture biosimilars, she explained, urging the Spanish authorities to invest more in the sector.

**Increasing generics’ price**

In the case of generics, one of the possibilities for preserving their profitability would be “to be able to increase prices by at least 10%.”

“We are not alone in this. Countries like Portugal have developed a rule that all medicines under 10 euros will have a 5% increase. That is an important relief,” said Rodríguez de la Cuerda.

The price of pharmaceuticals in Spain has evolved very differently from the consumer price index set by the National Statistics Institute (INE).

In this sense, the Spanish pharmaceutical industry, which is part of Farmaindustria, stresses that, rather than economic aid, it would be necessary to change the current regulation so that factors such as inflation do not have such a negative impact on the sector.

One solution could be to exclude strategic drugs from reference prices, as this would make it “easier to guarantee their supply”, according to Farmaindustria sources.
Rising inflation has exposed an already "complex" and "unsustainable" pricing system for generic drugs, driving manufacturers to the edge, often forcing them to pull their products out of the market, stakeholders told EURACTIV Slovakia.

The Slovak Ministry of Health has updated legislation to reflect the increased production costs, but the pharma industry insists it is insufficient.

The annual inflation rate in Slovakia has reached 15.4% driving medicine prices up threefold in some cases, says Ondrej Sukeľ, president of the Slovak Chamber of Pharmacy.

Mainly affected are the so-called over-the-counter medicines, which can be sold directly to people without a prescription and are not covered by public health insurance.

However, the situation for drugs sold at prices set by law is comparable.

Although the cost of production has risen as well, it cannot be reflected in the final price of the medicine. According to European manufacturers, such production is, therefore, unsustainable.

In particular, the generics sector, which is also subject to regulation in Slovakia, reports problems.

As the country is not self-sufficient in drug production, the challenges for manufacturers are ultimately felt even more. Small domestic pharma producers manufacture only pharmaceutical substances, the price of which is unregulated.

A complex pricing system

Representatives of the Association for Generic and Biosimilar Medicines of Slovakia (GENAS), which brings together 14 non-Slovak pharmaceutical companies, stressed that as a result of the crisis in the last six months, the costs of shipping have increased sevenfold and air transport fourfold.

Rising production and distribution costs are, therefore one of the reasons for stock shortages in Slovak pharmacies. Yet according to the law, the manufacturer is responsible for their availability.

"The Slovak Chamber of Pharmacists has long warned of the unsustainability of the current pricing of medicines and the unprofitability of dispensing prescription medicines," Sukeľ told EURACTIV Slovakia.

"What today constitutes the income of all pharmacies for the dispensing of prescription drugs is not even sufficient to pay the salaries of pharmacists," added the president of the Chamber of Pharmacists.

According to the GENAS Association, the reason is mostly the complicated pricing system.

"In Slovakia, we have one of the most regulated, and at the same time, strictest pricing policies for reimbursement of generic and biosimilar medicines," the Association's President, Terézia Szádocka explains.

For example, GENAS consider the manufacturers' obligation to adjust the prices of drugs every six months to be problematic.
“The Slovak Chamber of Pharmacists has long warned of the unsustainability of the current pricing of medicines and the unprofitability of dispensing prescription medicines,” Sukeľ told EURACTIV Slovakia. [Shutterstock/I viewfinder]
In practice, manufacturers must adjust their prices twice a year to the average of the three cheapest bills on the European market.

If this average drops the drug must become cheaper in Slovakia. However, if the average European price increases, nothing changes for the Slovak market, as the law does not allow for price increases.

According to GENAS, these conditions ultimately force manufacturers to cancel the registration of a drug on the Slovak market, meaning a drug is withdrawn. As a result, the patient is left with fewer choices, more expensive substitutes and originals, or simply no alternative.

“It would be most helpful to align the frequency of referencing with the international recommendation of EURIPID (European Medicines Price Database, ed.) in the sense to adjust it once every two years, and not twice a year, as it has been enacted in Slovakia for a long time,” say the representatives of the Association.

In this case, prices would be less threatened by fluctuations on the European market and the industry would be able to plan its pricing more predictably.

Contacted by EURACTIV Slovakia, the Health Ministry says it has not received any requests from the pharmaceutical industry.

The ministry of health reacted by the introduction of an amendment to the law on reimbursement for medicines.

Yet the industry is not satisfied. It claims that the amendment does not sufficiently address the impact of inflation and the energy crisis on the generic pharmaceutical sector.

**The amendment**

In August 2022, the Slovak Health Ministry issued an amendment to the Act on the Scope and Conditions of Reimbursement of Drugs.

However, it did not directly address the impact of inflation on their prices.

It only provided for the possibility to apply for special price regulation for a drug if there is a reason for this measure. The issue was therefore further addressed by the new decree, in force since February this year.

“Historically, this is the first opportunity for generic and biosimilar medicines to apply for a price increase of more than two to three percent, as the current legislation mandated until recently,” GENAS says.

According to the amendment, manufacturers will be able to exceed the European reference price, a kind of price ceiling for a drug, if the request is approved. The price will have a maximum limit determined by the average of the ten lowest prices instead of the standard three.

However, the Slovak Ministry of Health must conclude that the increase is justified. Moreover, the law does not specify what is considered relevant reasons for such regulation.

“A comprehensive solution to the medicines policy, also taking into account the persistent inflation and energy crisis by the state, could significantly contribute to ensuring the availability of medicines for Slovak patients,” Szádocka concluded.
A draft law tabled by the German government aims to avert drug shortages in the face of rising production costs. But generics producers warn that the plans are inadequate and broader price adjustments are needed to reach this goal.

Shortages of common drugs that plagued many EU countries at the start of this year have cast a spotlight on problems surrounding the security of supply, especially for generics, drugs that are no longer protected by patents. In Germany, shortages especially concerned children’s medicines and left many parents scrambling to find painkillers or fever medicines.

While part of the reason for the supply squeeze was an unusually high frequency of respiratory diseases after several years of lockdown measures, generics producers in the country have warned that the shortages revealed more structural problems concerning the pricing system for generic medicines.

While production costs are surging due to record-high inflation, the price at which producers can sell their drugs is limited by mandatory discounts put in place by the government to make medicines affordable for insurers and patients.

Squeezed in between these two factors, the industry warns, production has become economically unviable for many drugs.

“We expect that as a result of high inflation, individual generics will disappear from the market,” Bork Bretthauer, managing director of Pro Generika, the association of German generic and biosimilar companies, told EURACTIV Germany.

A survey conducted by the association among its member companies showed that within the next twelve months, companies will be forced to stop the production of one in ten generic drugs since it is no longer economically viable, he explained.

According to Bretthauer, antihypertensives, antidepressants, painkillers, and antibiotics are especially likely to be affected.

The draft bill, published on 14 February, “contains structural measures to strengthen the security of supply in the area of generic medicinal products”, a ministry spokesperson told EURACTIV Germany.

But rather than making general adjustments to the mandatory discount prices in place, the ministry’s approach is based on monitoring the situation and making individual price adjustments where and when need be.
To this end, the law will strengthen monitoring and assessment mechanisms on drug supply and establish an early warning system for potential shortages, the spokesperson explained.

“In the event of an emerging market constriction that carries the risk of a supply bottleneck, the ministry can take measures for fixed-price medicines and discounted medicinal products,” she added.

This more targeted approach is meant to limit the impact on those bearing the costs of more expensive medicines, according to the ministry.

**Too little, too late?**

But for Bretthauer, the law falls short of taking effective steps to make sure generics stay on the market.
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[Dmitry Kalinovsky/Shutterstock]
The law “will not be able to prevent market withdrawals – and does not even aspire to do so,” he said. “It has no relieving effect on the bulk of supply, and it does not provide any short-term relief for generic companies at any point.”

Bretthauer also pointed out that the bill focuses on antibiotics and painkillers and would thus only cover around 1% of generic drugs. “It does nothing for patients with heart disease, pain or depression,” he stressed.

Instead, Pro Generika wants the inclusion of criteria that would “allow producers to diversify production” in all mandatory discount contracts. Moreover, according to Bretthauer, price adjustments are needed for drugs not currently covered by the new bill.

**Are mandatory discounts the problem?**

In the view of public health insurers, however, the fixed prices for generics are not the key driver of drug shortages.

“The causes of supply bottlenecks are manifold, as various studies show,” Jens Ofiera from the umbrella organisation of German public health insurers (GKV) told EURACTIV Germany.

Instead, he argued, the high concentration of production on very few sites globally means any bottlenecks can have global ramifications. On a global market, Ofiera added, changes to Germany’s pricing system would only have a very small effect.

He also stressed that the association “regularly reviews the reference price market and adjusts reference prices to a changed market situation at appropriate intervals. This can mean lowering but also raising them.”

For Ofiera, the government should take steps “to structurally address the existing supply problems in the provision of medicines. Allowing the pharmaceutical industry to charge purely higher prices is not a sustainable solution.”
Italy urged to address almost €1 billion rise in generics’ production cost

By Giorgia Colucci | EURACTIV.it

Languages: Italian

The sharp rise of generic drugs’ production costs on the back of high inflation has caused the Italian government severe headaches, while the industry describes an “unsustainable” situation which could negatively impact patients.

Inflation, combined with the economic impact of the pandemic and the war in Ukraine, has put a serious strain on the generic drug supply chain.

In 2022, the total production costs of generic medicines in Italy increased by 21% compared to 2021, amounting about €937 million, according to the Nomisma Observatory on the Generic Medicines Industrial System data.

In particular, the cost of active ingredients and excipients is up 26.5%, the cost of transportation is up 100%, while the price of energy even showed an increase of 300%.

Enrique Häusermann, president of Egualia (Italian Association of Generic, Biosimilar and Value Added Medicines Industries), told EURACTIV Italy that this comes on top of the 2019-2021 period during which companies had to absorb significant price pressures along the supply chain.

“While all suppliers are increasing their costs, companies in the industry cannot adjust their price lists. Drug prices are set at the national level, and very often equivalent medicines are subject to additional non-negotiable containment measures”, he added.

Cheap drugs at risk

The main issue is that in Italy, prescription drugs have the lowest average prices in Europe, and margins have been cut by rising costs, raising the issue of manufacturing sustainability.

As many as 26% of equivalent drugs sold in pharmacies in Italy are priced at €5 or less.

Häusermann says these are the drugs most at risk of industrial sustainability, along with all sterile injectable forms sold to hospitals, which include essential and life-saving drugs, like many oncology drugs.

The current regulation of generic-equivalent drug prices does not allow any adjustment for inflation for drugs reimbursed by the National Health System and makes it impossible to renegotiate prices for public procurement procedures.

“This impasse is likely to result in future supply disruptions or the withdrawal of the relevant products from the market,” Häusermann said.

In fact, this has already happened. In the list of 3,200 deficient drugs on Italian Medicines Agency’s (Aifa) list, about half are products that have been absent from the Italian market for many years, some more than a decade.

“These are products of little interest to companies, but which have not generated problems for consumers”, Aifa’s president Domenico Di Giorgio told EURACTIV Italy.

Further shortages, however, could have a more significant impact.

The equivalents industry supplies an average of about 30% of national pharmaceutical consumption, and particularly in hospital supplies, there are
entire therapeutic areas where equivalents companies supply more than 70% of the annual need for medicines that are fully paid for by the National Health Service and free to the individual citizen.

**How to act on prices**

Egualia urges the government to intervene. First and foremost, a way must be quickly identified for an extraordinary review of low-cost drug prices in cases where there are risks to industrial sustainability.

“We think that the range (of drugs) up to €5 is the one most at risk,” said Häusermann, highlighting up drugs such as metformin and amoxicillin as examples.

It will also be essential to revise the criteria for managing the bidding process, favoring framework agreements for off-patent drugs, with the aim of safeguarding “the presence of multiple players in the market and the mitigation of the risks of product supply disruption”.

According to Egualia, the payback (or reimbursement) mechanism, demanded by companies for drugs on the substitution list sold in pharmacies should then be cancelled, and the one demanded on drugs sold through tenders in hospitals remodelled.

“For hospital supplies, in particular, there is a need for a legal rule and a special fund dedicated to the adjustment of contract prices by regional purchasing centers, which would allow the revision of prices for ongoing supply contracts”, Häusermann explained.

He also highlighted the need for a shared industrial policy in Europe identifying tools to support investments in pharmaceutical
production of active ingredients and finished products.

“Only in this way, by overcoming the limitation of state aid, could we ensure that the pharmaceutical industry has a production chain that is more controllable, safe and durable over time,” he said.

“Every single month exposes our production lines to an increasing risk of plant downtime. And it must be said that the shortage of raw materials will be the key issue for all world production systems for at least the next five years,” Häusermann added.

Italy’s health ministry was not available to provide a comment on the matter.

**A difficult situation for branded products as well**

For Marcello Cattani, president of Farmindustria, the Italian pharma industry association, drug production may no longer be sustainable for companies in the short term, because of inflation.

“We need to reason with Aifa on how to adjust prices, without burdening consumers too much”, he told EURACTIV Italy.

Cattani emphasised the low-cost drugs such as neuroleptics, antibiotics, antihypertensives, and diuretics, which were already in short supply in the autumn of 2022.

Production costs for Farmindustria member industries, compared to January 2021, have risen on average 40%.

Especially impactful were high energy prices, distribution costs, and higher prices for raw materials such as aluminum (used for blisters and packaging), paper, plastic, and glass. The weakness of the euro-dollar exchange rate in international trade also complicated the situation.

Prices do not guarantee affordability even for branded medicines. Non-reimbursable drugs have been eligible for price increases by law since 2005. However, these account for only 12% of the total and are worth €3.5 billion of the industry’s €29.6 billion of revenues in 2021. The rest are drugs that have fixed or declining prices.

“We need to open a discussion table because otherwise the situation will not be sustainable for a long time,” Cattani concluded.

In particular, the cost of active ingredients and excipients is up 26.5%, the cost of transportation is up 100%, while the price of energy even showed an increase of 300%. [Shutterstock/Daniele Mezzadri]
Polish pharma industry warns of manufacturing exodus

By Bartosz Sieniowski | EURACTIV.pl

Poland must support the domestic pharma industry to address the rising production cost of medicines, including generics, to compete with Asia and avoid a potential manufacturers’ exodus, Krzysztof Kopeć, Head of the Polish Association of Employers of the Pharmaceutical Industry (PZPPF), told EURACTIV Poland.

Kopeć believes any step towards the indexation of drug prices would strengthen EU competitiveness vis-à-vis Asia.

“The problems in the market for medicines to date may ultimately lead to manufacturers moving outside Poland, and it is a pity to lose the production capacity we have today. It is important to stimulate and support the domestic pharmaceutical industry in order to strengthen the EU’s competitiveness towards Asia,” he said.

A perfect storm of factors has contributed to inflation in the EU reaching levels unseen in the last decade and increased prices in every area of economic activity, from shipping to raw materials and energy.

The generic drugs industry has been severely affected by drug shortages, especially due to national price caps. Several cheap drugs have now disappeared from the market because they have become economically unviable to produce, directly impacting patients in need.

Generic medicines are extremely popular in Poland, accounting for 88% of the country’s drug market in terms of value and 66% of volume.

Many pharmacies sell patients generics on their request, even if their prescriptions include original, more expensive medicines.

“The pharmaceutical market in Poland is worth 45 billion zlotys (€9.612 billion), and its dynamics are growing. The key medicines for basic diseases are reimbursed,” Kopeć said.
"In the case of non-reimbursed medicines, inflation increases their market prices. With reimbursed medicines, the prices are controlled top-down. Stable prices of such medicines, combined with rising energy prices and the falling purchasing value of money, leads to a situation where production of medicines becomes unprofitable," he said.

"No company wants to function as a charity organisation. Companies need funds to function on the market," Kopeć added.

He said there are relevant institutions that can help with individual requests for financial assistance for the continued production of medicines. However, this process can be extremely long, as each application is considered individually.

"We discuss with the health ministry the introduction of price indexation of reimbursed medicines in Poland, i.e. linking them to current economic factors in the country, such as salaries or the inflation rate," Kopeć said, adding that similar solutions are already applied in other EU countries such as Portugal, Romania and Bulgaria, while discussions are also ongoing in Germany and France.

"Yet, for the time being, the ministry prefers to support the market of medicines, including generic medicines, using individual subsidies," he said.

**Production more expensive but safer than Asia**

Grzegorz Rychwalski, PZPPF’s deputy head, told EURACTIV Poland that it’s urgent that EU institutions take steps to bring the pharma industry back to Europe.

"In May last year, we submitted a petition to the European Parliament that recognises the production of active substances as a critical infrastructure for safety [...] We want the manufacturing of medicines to be safe and not necessarily as profitable as possible. Currently, European medicines are produced in Asia because they are the cheapest," he said.

The petition was submitted to the relevant committees in the European Parliament, and a hearing took place in July 2022.

"All MEPs present, irrespective of party affiliation, considered our petition relevant and that action was needed to take it forward. An external study was commissioned on what conditions must be in place for this to happen. We are still waiting for the publication of the results, but we expect that this could take place later this month," Rychwalski said.

PZPPF hopes the study will serve as a basis for a resolution by the European Parliament that will oblige the Commission to propose legislation that will “bring European drug production back to our continent”.

Production of medicines in Europe “will obviously be more expensive than if it continued in Asia, but it will also be safer”.

“Besides, shortening the supply chain will allow us to get rid of the problem of possible transport disruptions, which may allow for the price of medicines to be reduced,” Rychwalski concluded.
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