

Pandemic ready Europe:

Modernising Medicines Regulations and Supply Chain Security

1. Executive Summary

The EU Global Health Strategy, adopted in November 2022, aims to improve global health, strengthen health systems, and enhance pandemic preparedness through international cooperation and sustainable policies. And one of the most important part of it is to ensure global drug safety and accessibility involves both medicine quality and availability, a reality highlighted globally during the COVID-19 pandemic. Drawing from that crisis, the European Union established the Global Health Resilience Initiative in 2026. This framework updates the EU's strategy to prevent, prepare for, and respond to health threats, strengthen systems, and support partner health sovereignty.

2. The main challenges – how to ensure global drug safety?

There are five main paths to better coordinate Global Health Resilience, and all of them focus on securing drug safety.

1. Creating a more coordinated global health architecture

This path aims to improve EU teamwork on global health by boosting joint action and supporting a strong WHO. It also emphasizes the importance of diversifying global supply chains and the manufacturing of key health products. The COVID-19 pandemic showed us how dangerous border closures can be, as unequal access left some countries cut off from vital drugs and medical supplies.

FACT: Over 42% of €360 million of the Pandemic Fund's resources were provided by Team Europe

2. Diversifying global supply chains and manufacturing of key health products

Diversifying global supply chains and manufacturing for key health products is the primary lesson of the pandemic. The global industry faced severe supply chain disruptions, making the smooth flow of goods a major challenge. Shortages ranged from everyday items like toilet paper to critical medicines and vaccines, making the prevention and treatment of the Covid 19 difficult. The Global Health Resilience Initiative places emphasis on the fact that every state must ensure the availability of medications for its own citizens. Just in case.

FACT: €75 million investment in Biovac in South Africa was already announced by the EU

3. Reinforcing prevention, preparedness and response to global health threats

The last few years have shown us – all around the world – how vital global health readiness is. A health crisis anywhere affects everyone everywhere, making medicine availability crucial. The main premise of the strategy is the strengthening of global surveillance, laboratories, and epidemic intelligence ensuring faster detection, access to vaccines and treatment through EU and global partnerships.

FACT: Over €100 million in health security initiatives were launched together with Africa CDC

4. Supporting resilient, country-led health systems

The main goal is to support countries in building stronger health systems through dedicated funds and shared knowledge to improve the local healthcare. We can do this by promoting primary care and universal coverage, especially in crisis affected areas. A healthy population leads to a healthy state. However, true public health requires reliable access to essential medicines and medical products, which remains a core responsibility of the state.

FACT: €75 million investment in Biovac in South Africa was announced by the EU already

5. Bolstering societal resilience by fostering trust in science and countering health dis/misinformation

The COVID-19 pandemic has shown us how people react to medical statements and recommendations. The main goal should be to share reliable knowledge about medicines, treatments, and vaccines. We believe that no matter which country you were born in, everyone deserves equal treatment.

The Global Health Resilience Initiative supports access to reliable scientific data and strengthens public health communication, which is crucial during health crises. We believe that fostering trust in science and evidence-based policymaking builds societal resilience. Every nation should ensure its citizens have equal access to effective treatment methods.

FACT: €700 million pledged from the EU to the Global Fund, bringing Team Europe's total contribution to over €3 billion

3. Key industrial challenges for Critical Medicines

According to Critical Medicines Alliance medicine shortages affect all drug types, but they hit older, off-patent, and generic medicines hardest. This issue stems largely from the low profit margins associated with these products, which discourage investment in strong manufacturing capacity. At the same time EU health systems rely heavily on generic medicines, prioritizing low costs to reduce national healthcare budgets.

As a result, states must do more than fund new drugs and new pharmaceutical investments. They also have a responsibility to maintain the production of medicines that are already available.

The Union List of Critical Medicines mostly comprises generic, off-patent medicines that no longer benefit from intellectual property rights or other regulatory data protections. These affordable products are staples of EU health systems but their production patterns increasingly heighten vulnerability. Many critical medicines are supplied by only one or two manufacturers, leaving supply chains highly fragile and dependent.

According to report by Grumiller and Grohs, these suppliers have often outsourced manufacturing processes or moved production of their finished product outside of the EU and/or source their API from outside the EU. As a result, the EU is reliant, for many of its critical medicines, on a limited number of APIs suppliers or manufacturers, many situated outside of the EU. For generic medicines, it has been calculated that between 60 to 80% of the API production has been outsourced to China over the recent years and an increasing part of other inputs to the manufacturing supply chain are being outsourced to Asia.

This is a real threat to the availability of medicines in Europe. We are talking about a vital market that affects the safety of everyone.

Critical Medicines Alliance identified the following key industrial challenges:

- Overreliance on a limited number of geographical locations for the provision of API and raw materials, which is of high importance for both generics and originators;
- **Erosion of the EU manufacturing base**, starting upstream of the supply chain as well as for marketing authorisation holders - especially for generics (90% of the Critical Medicines list), but also for innovative medicines;
- Clear market consolidation which encourages **single supplier sourcing** inside and outside of the EU;
- Lack of competitiveness and investment in the European API industry as well as in the generics industry.

The Critical Medicines Alliances considers that the above challenges should be addressed in priority in a future Critical Medicines Act, while other policy instruments should be developed to address non legislative challenges.

5. Sources

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