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Building strategic independence for the European pharmaceutical industry

EVENT REPORT



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The COVID-19 pandemic demonstrated both the extent of our economies' reliance on global supply chains – not least in the supply of medicines – as well as the importance of exchange of knowledge and goods. This has led many European countries to call for 'strategic autonomy' to boost the continent's resilience towards external shocks. Based on its well-established single market regulatory frameworks, the European Union has re-focused investments towards the goal of strategic autonomy and has announced legislative proposals to this end in 2022.

The 'Building strategic independence for the European pharmaceutical industry' debate on 22 March 2022 brought together representatives from European Commission and European Parliament, research, health economics and industry to discuss where the problems lie in pharmaceutical supply chains and what can be done to remedy the issues.

A recording of this event can be found at [here](#).

Shortage of medications: a chronic, long-standing problem

The pandemic shone a light on long-standing supply issues. Participants discussed where these problems lie and how we can better understand them.

"Access to stable and sufficient supplies of medications really does make the difference between sickness and health, but in many countries, there have been stockpiles or delayed access to medicines," said **Thyra de Jongh**, Principal Consultant at Technopolis Group and Lead Author of the report, '[Future-proofing pharmaceutical legislation: study on medicine shortages](#)', published by the European Commission in 2021.

Shortages happen most frequently with older, cheaper products on the one hand and more complex and innovative medicines on the other, said de Jongh, with about half the problems being due to quality issues in manufacturing, although a lack of data hinders efforts to discover where the problems lie.

Another key factor is sudden increases in demand, which reveal lack of resilience in supply chains. Shortages are often localised, with problems in one country but plentiful supplies in others.

An OECD study, entitled '[Shortages of medicines in OECD countries](#)', described by **Ruth Lopert**, Senior Health Economist at the Organisation for Economic Co-operation and Development (OECD), found many similar issues. For example, it found that shortages increased by 60% from 2017 to 2019 – before the pandemic had taken hold in Europe. However, its research suggested that in about two-thirds of cases, shortages were occurring in many different countries at the same time.

Technopolis' recommendations include the creation of a harmonised EU-wide definition of medicine shortages, harmonised reporting criteria for shortages, and an EU-wide list of medicines where shortages are most critical.

It also called for legislation to ensure notification requirements are met; requirements for suppliers to have adequate shortage prevention and mitigation plans in place;

greater flexibility for emergency imports; more diversified tenders; an accelerated mutual recognition procedure (MRP) within the EU; an EU-wide medicines packaging and labelling regulation; and information about available alternative medicines in shortage databases.

Data challenge

The lack of good quality data and intelligence was raised several times during the debate. Differences in reporting and definitions of shortages are an issue.

“There is a challenge in getting robust, comprehensive data on which to base policies,” pointed out **Giacomo Mattinò**, Head of Unit for Food, Retail, and Health at the European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs.

It is very difficult to do clear cross-border analysis on shortages because of differences in nomenclature, perspective, definition and even how notifications are made, added Lopert. “There is a need for greater harmonisation not just across Europe but globally. Good policy requires good data.”

Elke Groote, Head of EU Relations at Novartis, added: “We are asking the EU to make sure there are harmonised definitions and shortage reporting requirements. It will help provide a better view of where the shortages are.”

“The COVID-19 crisis revealed shortages of equipment in hospitals and deepened medication shortages and the need to reduce external dependencies,” said **Cristian-Silviu Buşoi**, Chair of the European Parliament’s Committee on Industry, Research and Energy (ITRE). “It also highlighted the need to boost innovation and invest more on health in general.”

Need to reinforce strategic autonomy

Strategic autonomy – a push towards resilience – is now a priority for the EU. Participants discussed what that means for pharmaceuticals and how pharmaceutical strategy intersects with wider industrial policy.

The pandemic has made clear the need for the EU to reinforce its strategic autonomy in pharmaceuticals, added Mattinò. “The challenge is to make a synthesis between public health and industrial policy so they don’t contradict each other. It is important to keep borders open and address the need for free movement of goods,” he said.

The pharmaceutical industry is critically important to the EU, said Buşoi. “The industry in Europe is uniquely placed to play a key role in our economic recovery, resilience and future growth, but only if the innovation drivers are in place and if the appropriate financial support accompanies the legislative framework.”

“Sustaining and growing the pharmaceutical industry in Europe depends on creating a policy framework that supports the evolution of regional innovative manufacturing ecosystems and an industrial strategy that ensures Europe remains competitive in the face of intense competition from other regions,” he added. “Where innovation happens matters – for jobs, resilience and economic growth, as well as to patients and healthcare systems across the EU.”

Increasing preparedness

The pandemic highlighted vulnerability and the need to be prepared for future disruptions. The debate considered what can be done to build resilience and preparedness.

The EU has been working hard to improve its preparedness for the next pandemic, with the launch of the European Health Emergency Response Activity (HERA), which aims to bolster the EU's "development, manufacture, procurement and distribution of key medical countermeasures in case of a health emergency," said Mattinò.

There is also scope for healthcare projects under the new Important Projects of Common European Interest (IPCEI) initiative. "This is an instrument to support member states to pool investments to support innovation and to mobilise public and private funding for cross-border disruptive projects," he added.

"A risk we have seen in the pandemic is that, at European or global level, blocs tend to close to each other with excessive protectionist measures. The European pharmaceutical industry is strong and open and we have to keep this openness."

According to Groote, "we were dealing with closing borders and disrupted transport. What was important was good collaboration with all stakeholders, including European institutions."

She highlighted that Novartis has robust continuity plans, including safety stocks, not just of medications but also ingredients essential to their manufacture. "For many products we have dual sourcing so that if one source comes under pressure, we can go to another," she added.

Manufacturers had to deal with not only supply disruptions but huge demand peaks as well. For example, demand for some ICU medications rose 300% to 400%, "often not because patient numbers went up but because of hoarding by hospitals or regional and national authorities".

Possible solutions include moving from price-only tenders to "smart procurement", which considers issues such as environmental sustainability and security of supply, she added.

Conclusions

As moderator and Senior Fellow at Friends of Europe, **Tamsin Rose**, pointed out in her conclusion, "this is a problem that existed well before the pandemic. It's partly about distribution, partly about manufacturing. There are questions about how we procure – competitive tenders where the winner takes all mean there is no incentive for the losers to continue making products."

To tackle medication shortages in the EU and ensure the bloc is better prepared for the next pandemic, more data is crucial, but that data must be consistent and harmonised across member states. It is also vital to foster a strong EU pharmaceutical industry, as well as open access to producers from around the world.

Recommendations

- Harmonisation of the definition of shortages
- Harmonisation of reporting criteria
- Stronger consideration of the links between pharmaceutical and industrial policies
- Better collaboration and communication between partners to keep trade open and flowing
- Move towards smart procurement

