friends of europe

EVENT REPORT

Ambition versus reality: reflections and reactions to the revision of the general pharma legislation

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Event report

This report reflects statements and questions made during a dinner debate held under the Chatham House Rule and hosted by Friends of Europe in Brussels on 23 May 2023. The event was held shortly after the European Commission published the proposed revision to the EU's pharmaceutical legislation – the largest reform in over 20 years – to make it more agile, flexible and adapted to the needs of citizens and businesses in Europe.

Event summary

Catching the innovation boat

Speakers agreed that Europe relies on innovation in healthcare. The pharmaceutical sector represents a crucial player in Europe's economy in terms of jobs, skills and innovation, but investment is declining. Today, only 1 in 5 of all new treatments come from Europe compared to 50% just 25 years ago.

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> **Nathalie Moll**, Director-General of the European Federation of Pharmaceutical Industries and Associations (EFPIA)

When it comes to stimulating more research and development in Europe, the EU proposal "completely misses the boat," said **Nathalie Moll**, Director-General of the European Federation of Pharmaceutical Industries and Associations (EFPIA). "We have an opportunity to reverse the trend and create a regulatory framework that protects Europe's attractiveness for innovative companies" she added.

Audience interventions added that, although on paper the EU offers more incentives for innovative pharmaceuticals than the US, in practice the whole US healthcare framework is more conducive to research and development of innovative therapies.

Susana Solís Pérez, Member of the European Parliament, was one of several participants to support the objectives of the reform and assert that it should strike the right balance between access to medicines and a competitive pharmaceutical industry. "This is a historic opportunity to modernise our healthcare systems," Solís Pérez said, but the review "needs to offer security and protection so innovation happens in Europe and not elsewhere."

A number of industry representatives added that when it comes to pharmaceuticals, there are innovation and market access problems that need to be fixed immediately, rather than as part of a legislative review that is likely to take years to negotiate and implement given its ambitions.

SMEs, in particular, are the pharmaceutical companies that struggle to raise capital and bring innovation to market, for instance, if the period of regulatory protection were to be reduced as part of the review and conditions outside their control attached getting back years of protection.

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> **Susana Solís Pérez**, Member of the European Parliament

The audience was reminded that the first two vaccines against coronavirus would not have emerged without partnerships between small and large companies. For one, life sciences company BioNTech partnered with Pfizer, while for the other, research at the University of Oxford was supported by AstraZeneca.

New working relationships

The pandemic also promoted a view of healthcare that was very different before 2020. In particular, it made citizens aware of unacceptable differences between national healthcare systems. This means a truly European approach to pharmaceuticals was developed, specifically regarding the procurement and distribution of vaccines.

As one participant put it: people say COVID-19 changed the world, but in Europe what changed is the policy response. Faced with a global pandemic, the EU was able to assume responsibility for things that had previously been entirely national competencies.

The pharma reform hopes to build on this ‘European health union’ approach and foster the new solidarity between EU and national authorities. At the same time, some participants at the dinner argued that different national specificities mean there will always be a need for some different rules to allow for different situations.

This led to another cautious remark about the emerging post-pandemic working relationship. “We need to avoid a battle between what often is presented as citizens and industry’s conflicting interests,” as one stakeholder said.

Many of the gaps and problems in European healthcare systems have been clear for a long time, but as Friends of Europe’s event moderator **Tamsin Rose**, put it: “COVID-19 put a spotlight on them.”

Access all areas?

Moving forward, participants from across all sectors agreed that access to pharmaceuticals is likely to be one of the main challenges to and biggest opportunities for building citizen trust. **Åsa Kumlin**, EU Coordinator at the Swedish Medical Products Agency, noted that the main objective of the review was to ensure that treatments "reach all citizens, at an affordable price."

The root causes of unavailability and delay to medicines are multifactorial, including the price and reimbursement process in Member States, health system readiness and commercial decisions.

Companies launching a product in a large economy are then likely to have problems accessing smaller markets on similar terms. Affordability, for instance, remains one of the drivers of access and this is not necessarily an EU competency.

All of these complex access problems are particularly acute when it comes to innovative medicines, the dinner debate heard. Bearing this in mind, the COVID-19 response is not necessarily considered as replicable for market access, when it comes to overhauling national pharmaceutical markets.

Opinions were divided over a proposal to address antimicrobial resistance (AMR) through new incentives like a 'vouchers' system. Under this system, developers of novel treatments would be given an extra year of data protection on another drug to compensate for limited sales prospects.

Some felt an AMR voucher was a good model to direct investment in the new antimicrobials. Others, however, argued that while new antibodies are needed for AMR and member states are willing to work together on incentives, they do not need the voucher.

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> **Åsa Kumlin,** EU Coordinator at the Swedish Medical Products Agency

Proposals and way forward

1. Promote long-term stability for patients and novel investments

Europe now has a once in a lifetime opportunity to update its package of pharmaceutical legislation. If properly managed, the proposed review will bring benefits to citizens, industry and healthcare systems. The challenge of creating a stable policy framework for patients and investors in the face of global competition is, however, set to dog negotiations. The EU must find ways to incentivise innovation on a common market with no common EU healthcare system.

Ways forward

- Prioritise the subject of incentives in talks, particularly regarding how to attract the most innovative pharma developments to Europe.
- Explore mechanisms to promote access to both innovative and generic medicines.
- Further consult on AMR vouchers to address divisions over effectiveness and alternatives.
- Examine public investments in R&D and pharmaceutical innovation.
- Identify and address shortcomings in the Cross-border Healthcare Directive.
- Examine the implementation of the Health Technology Assessment (HTA) Regulation as a way to harmonize reimbursement rules and speed up access to medicines.

2. Build an EU approach to healthcare around lessons learned during the coronavirus pandemic

The coronavirus pandemic saw Europeans and European companies unite around common pharmaceutical objectives as never before. The benefit of large companies working with SMEs and researchers to achieve a common goal at great speed and across borders was clearly demonstrated to patients. The goodwill and solidarity shown during the pandemic should be used as the basis of a new European approach to healthcare.

Ways forward

- Maintain consumer respect for pharmaceuticals gained during the development of vaccines through, for instance, public-private partnerships and joint industry undertakings.
- Consider how Europe competes and can add value internationally.
- Maintain a system of strong and predictable incentives, including for the benefit of SMEs.Foster the role of and investments made by SMEs as the source of pharma breakthroughs.
- Maintain capacity and competence at national level, even as more is done on health at the EU level.
- Recall and respect the role played by the European regulatory network in the assessment and approval of medicines and of national authorities in pricing and reimbursement of medicines.

3. Keep talking and build trust

Closed-door debates like this Friends of Europe dinner show the importance of building trust between different interest groups at all stages of negotiations. Patients, however, remain wary of industry interest and there is a perceived conflict between citizens and pharmaceutical companies' interests.

Ways forward

- Promote events at which participants can openly discuss the opportunities and challenges ahead.
- Build trust through dialogue and adaptation.
- Avoid artificial divides between industry and citizens, for instance, by countering populist claims through clear information.
- Improve patient awareness of healthcare rights, particularly across borders.
- Engage with patients to explain the pharmaceutical products and procedures that are available.
- Work closely with patients whenever possible because proximity builds trust.
- Seek opportunities for policy to encourage transparent social security coordination between member states.
- Establish a High-Level Forum to discuss Access to medicines.

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