

Pharmaceutical Innovation Summit

Bridging competitiveness with affordability

Brussels, 5 May 2026

Conference report



The poster features a large, stylized DNA double helix structure in blue and orange, winding diagonally across the background. At the top left, the esip 30 1996 2026 logo is displayed. At the top right, the MEDEV Medicine Evaluation Committee logo is shown. The main title 'Pharmaceutical Innovation Summit' is centered in large white font, followed by the subtitle 'Bridging competitiveness with affordability' in a smaller white font. Below this, the date 'Brussels | 5 May 2026' is listed, followed by the time 'From 09:00 to 13:00' and the note 'Followed by a networking lunch'. At the bottom, the 'Venue' is specified as 'AT60 House of Austrian Economy' and 'Av. de Cortenbergh 60, 1000 Brussels'.

esip 30
1996 2026
EUROPEAN SOCIAL INSURANCE PLATFORM

MEDEV
Medicine Evaluation Committee

**Pharmaceutical
Innovation Summit**

*Bridging competitiveness
with affordability*

Brussels | 5 May 2026

From 09:00 to 13:00
Followed by a networking lunch

Venue
AT60 House of Austrian Economy
Av. de Cortenbergh 60, 1000 Brussels

Context and objectives of the Summit

On 5 May 2026, the European Social Insurance Platform (ESIP) and the Medicine Evaluation Committee (MEDEV) organised the high-level conference “Pharmaceutical Innovation Summit: Bridging competitiveness with affordability”. The Summit took place in Brussels and gathered European and national decision-makers, leaders from health technology assessment-HTA and pricing and reimbursement-P&R authorities, regulators and industry representatives to discuss whether and how pharmaceutical innovation can be steered towards meaningful health outcomes, while preserving the affordability and sustainability of solidarity-based health systems.

The debate took place at a moment of renewed political attention to Europe’s competitiveness, strategic autonomy and security of supply, and amid turbulent geopolitical developments. Participants returned to a common question: how can Europe remain attractive for innovation while ensuring that public resources reward real therapeutic value and deliver timely access for patients?

Programme

Summit venue: AT60 House of Austrian Economy, Avenue de Cortenbergh 60, 1000 Brussels.

Moderated by Yannis Natsis, Director, European Social Insurance Platform (ESIP).

Time	Session	Speakers
09:00 - 09:15	Opening remarks	Sandra Gallina, Director-General, DG SANTE, European Commission
09:15 - 10:15	Panel I - When evidence falls short: Implications for regulation and reimbursement	Emer Cooke, European Medicines Agency; Alexander Burz, DVSV; Birgitte Klindt Poulsen, Danish Medicines Council; Magnus Thyberg, TLV
10:15 - 11:15	Panel II - Paying for innovation: Incentives, competitiveness and competition in Europe	Thomas Fatôme, CNAM; César Hernández García, Spanish Ministry of Health; Stefanie Stoff-Ahnis, GKV-Spitzenverband; Adrian van den Hoven, Medicines for Europe
11:15 - 11:45	Coffee break	
11:45 - 12:45	Panel III - Geopolitics applied to pharmaceuticals	Murray Aitken, IQVIA Institute; Robert Ljoljo, ZZS; Tina Wang, CIRS
12:45 - 13:00	Closing remarks	Vytienis Andriukaitis, Member of the European Parliament
13:00 - 14:00	Networking lunch	

Opening remarks by Sandra Gallina



Sandra Gallina, Director-General of DG SANTE, European Commission, opened the Summit, situating the pharmaceutical debate within Europe's broader demographic, budgetary and geopolitical reality. She underlined that the European welfare model must be preserved but warned that the resources needed to safeguard it are increasingly difficult to secure. In the years ahead, competing challenges will sharpen the pressure on health systems and require policymakers to make choices that are both economically realistic and socially responsible.

The Commission's current reform agenda was presented as a response to these challenges. Gallina referred to a "glorious series" of health reforms, including the revision of the general pharmaceutical legislation and medical device rules, the Critical Medicines Act, the European Health Data Space, the proposed Biotech Act, and, not least, the upcoming multi-annual financial framework (MFN) including the proposal for a substantial Competitiveness Fund. Together, these initiatives are intended to modernise the regulatory environment, give industry a more predictable framework to support research and production, and equip Europe to translate innovation into better patient outcomes.

Panel I - When evidence falls short: Implications for regulation and reimbursement

The first panel brought together Emer Cooke (European Medicines Agency), Alexander Burz (Federation of Social Insurances - DSVS, Austria), Birgitte Klindt Poulsen (Danish Medicines Council) and Magnus Thyberg (Dental and Pharmaceutical Benefits Agency-TLV, Sweden).

The discussion focused on the consequences of uncertainty at the time of authorisation and reimbursement, and on how regulators, HTA bodies and payers can work together to ensure that evidence generated is relevant for decision-making across the product lifecycle.



From efficacy to effectiveness: defining what counts as innovation

Panellists discussed how the question "what is innovation?" should be assessed in relation to outcomes that matter for patients, the degree of unmet need, the quality of the evidence base and the associated costs for publicly funded systems. While highlighting that decision making on pharmaceuticals unfolds across several

stages, with distinct assessments of efficacy and effectiveness, participants agreed that the new EU HTA framework can provide pricing and reimbursement authorities with better data at an earlier stage. This, in turn, can support more informed decisions on which medicines should be purchased, when they should be made available and at what price, thereby strengthening payers' negotiating power.

"The EU HTA framework can provide better evidence, earlier. Joint scientific consultations can help companies understand what data will be needed, but manufacturers should actively engage with these processes for them to deliver value." (Birgitte Klindt Poulsen)



For payers, this is crucial. Reimbursement decisions need to be informed by clinical trial results and later supported by proof of effectiveness in real-world practice. To make this happen, more dynamic systems of evidence generation need to be explored. The debate therefore moved quickly to the type of evidence that is useful for decision-making.

"Innovation must be assessed through a health-economic lens: after regulatory approval, payers need to know what to buy, when to buy it and at what price." (Alexander Burz)

The evidence threshold and real-world data

The role of real-world data (RWD) was central throughout the panel. Magnus Thyberg emphasised the importance of collecting better and more complete data as early as possible, while Alexander Burz pointed to the potential of pay-for-performance and managed entry agreements, particularly where uncertainty remains at launch.

"Europe must make better use of real-world data to understand medicines earlier and more completely." (Magnus Thyberg)



Emer Cooke confirmed that patient relevance and clinical meaningfulness are cornerstones of regulatory decisions. In the global context, European regulators are often perceived as more demanding at the point of marketing authorisation compared to other international medicines regulators. It is therefore important to have more discussions across regulators, HTA bodies and healthcare payers on how much evidence and what type of evidence we need to enable innovation that can benefit European patients. She also noted opportunities in working together on post-launch evidence generation (PLEG) studies, particularly by ensuring that the evidence requirements are practicable for companies and aligned with patient needs. At the same time, she underlined evolving opportunities: the DARWIN EU network already provides experience in generating evidence after authorisation (RWD) and can act as a pathfinder for the European Health Data Space.

RWD models require high-quality data infrastructures, clear protocols and willingness from both companies and payers to share risk. Birgitte Klindt Poulsen noted that RWD protocols developed in dialogue with HTA bodies can help fill knowledge gaps, including in underserved areas where the EHDS may expand the evidence base.

Strengthening collaboration on regulatory, HTA and payer evidence requirements

The session closed with a shared call for closer cooperation while respecting the distinct responsibilities of each institution. Panellists underlined the need for better coordinated efforts of European regulators, HTA bodies and healthcare payers, also addressing perceived evidence gaps, particularly in light of growing external pressures that could affect access to pharmaceuticals in Europe.

“Regulators, HTA bodies and payers should not do each other’s jobs, but should collaborate so that the system can work more seamlessly.” (Emer Cooke)



Panel II - Paying for innovation: Incentives, competitiveness and competition in Europe



The second panel gathered Thomas Fatôme (CNAM, France), César Hernández García (Spanish Ministry of Health), Stefanie Stoff-Ahnis (GKV-Spitzenverband, Germany) and Adrian van den Hoven (Medicines for Europe). The debate addressed one of the Summit’s central tensions: Europe seeks to remain competitive and innovative, but health systems are facing steep expenditure growth and must preserve solidarity-based access.

Rising expenditure and the demand for value

Pharmaceuticals are a substantial health expenditure component, the second largest in Germany after hospital care, noted Stefanie Stoff-Ahnis, observing a sharp rise in spending in recent years. She pointed in particular to new active substances, whose costs have tripled, as well as rising volumes and high-cost combination products where added value is not always clear. To face rising expenditure, consideration was given to price-volume

regulation, stronger combination discounts and a better coordinated incentive framework that rewards competition and real innovation.

Thomas Fatôme described a similarly difficult outlook in France, pointing to a large health insurance deficit and rising costs per patient. He noted the growing number of medicines exceeding high annual cost thresholds. Prevention was highlighted as one route to long-term sustainability, but the immediate challenge remains how to ensure that prices reflect value and that public investment is visible in pricing discussions without becoming an open-ended budgetary commitment.

“Price should reflect value and public investment. In this context, it is important to define which health needs remain insufficiently addressed and where public investment should be targeted.” (Thomas Fatôme)



Global competitiveness, industrial policy and the role of payers

In light of global geopolitical turmoil affecting pharmaceutical policies, César Hernández García framed competitiveness not only through pharmaceutical investment, but especially through integrated cross-sectoral policies. As the audience emphasised that Europe is losing ground to the United States and China, Hernández

García stressed that the competitiveness gap was already evident before the debate on most-favoured-nation-MFN policies. Yet, Europe, with its 450 billion citizens and early access systems, preserves a competitive edge. The question is therefore how to build industrial capacity and supply resilience in ways that are practical, targeted and compatible with health system sustainability. At the same time, several panellists stressed that the mission of payers is to preserve solidarity-based access, rather than diverting limited resources to finance industrial policy tools.



“Social health insurance should cover health risks, not geopolitical risks, and the responsibility for industrial policy projects should be clearly assigned. This distinction is especially important when proposals to strengthen European production or extend exclusivities would impose significant costs on statutory health insurance systems.” (Stefanie Stoff-Ahnis)

Against this background, the ongoing discussion on the Biotech Act and the extension of intellectual property rights through supplementary protection certificates-SPC raises concerns. Participants questioned whether an extension of protection for biotechnology-derived products would meaningfully address Europe’s competitiveness challenges, particularly knowing that the resulting costs would be borne by social health insurers and patients thereof.

Competition, generics and biosimilars as affordability levers

Adrian van den Hoven highlighted the off-patent sector’s contribution to efficiency and savings, pointing to the significant untapped potential in biosimilars. Many biologics losing exclusivity over the next 10 years still have no biosimilar known to be under development. Without biosimilar competition, healthcare systems will face higher costs and fewer opportunities to expand access to biosimilars. In this context, levers in the Biotech Act, as well as national incentives for biosimilar development along with regulatory guidance from EMA and the Heads of Medicines Agencies could help reduce the biosimilar void. Moreover, dialogue with health insurers like ESIP and

MEDEV could incentivise biosimilar manufacturers to develop for markets where it is harder to create competition, i.e. orphan drug markets.

The panel also discussed procurement and tendering design. According to van den Hoven, abnormally low bids may incentivise delocalisation, while single-winner tenders can accelerate consolidation and reduce resilience. Multi-winner tenders, along with competition-friendly policies and targeted incentives for biosimilar development and uptake measures were identified as instruments that can support both affordability and supply security.

In conclusion, panellists warned that competitiveness cannot be promoted through rewards alone. Integrated policies are needed to ensure that incentives are proportionate and well-targeted.

“Integrated policies are needed to avoid excessive incentives. Competition is also important. We need access to a plurality of products, while ensuring that production facilities are able to respond to actual health needs. This requires a pragmatic and cross-sectoral discussion on how pharmaceutical and industrial policies should be designed and implemented.” (César Hernández García)



Panel III - Geopolitics applied to pharmaceuticals

The third panel, with Murray Aitken (IQVIA Institute), Robert Ljoljo (Slovenian Health Insurance Institute - ZZZS) and Tina Wang (Centre for Innovation in Regulatory Science - CIRS), placed Europe's pharmaceutical policy debate in a global context. Speakers assessed the implications of United States pricing policy, as well as China's rapid regulatory and industrial development.



The United States' most-favoured-nation policy: a path of uncertainty



Murray Aitken described the “America First” logic currently shaping US pharmaceutical policy, centred on faster access to medicines for US citizens, increased domestic production and lower prices. However, whether the most-favoured-nation (MFN) debate will effectively reduce prices in the US remains questionable. While the MFN policy is expected to be presented ahead of the November mid-term elections, the surrounding debate is characterised by significant uncertainty.

For European payers, the concern is that external pricing pressures could worsen launch delays or make Europe a less attractive market. Yet the

focus on price alone can obscure the role of volumes, market and regulatory structures, with Europe’s strength lying in its large population, solid institutional basis and solidarity-based access model.

China’s road of change towards strengthening pharmaceutical innovation

Tina Wang explained that China has moved from being a late-launch market to an earlier-submission market and a forefront innovation actor. This shift was supported by regulatory reforms, faster approvals and a growing domestic innovation base. As a result, the number of innovative medicines has multiplied in recent years, and China is increasingly seen by international companies not only as a sales market, but also as a place for co-development and business partnerships.

China’s payer reforms were also discussed. Since 2018, China has updated its national reimbursement list every year, giving payers a stronger role in negotiating reimbursement decisions. At the same time, China has also introduced commercial health insurance lists as an additional pathway. Overall, Wang described a gradual shift from pure price reduction towards more value-based decision-making, including through patient involvement and real-world evidence assessment protocols across the product lifecycle, with price flexibility linked to evidence generation commitments.

China’s approach was characterised as deliberate and rational: China is seeking to promote innovation, recognising high-risk and high-cost research and development. While the US is increasingly pressured by China’s rapid rise in pharmaceuticals, Europe faces both a competitive challenge and an opportunity to learn from a system that is actively aligning regulatory tools, negotiating strength and industrial objectives.



Turning Europe's scale into a stronger single market

In this complex global pharmaceutical ecosystem, Robert Ljoljo underlined Europe's position, pointing to both challenges and opportunities. While the EU benefits from high volumes and a stable regulatory framework, it also remains a fragmented market of 27 national systems with significant production and supply dependencies. This



fragmentation is particularly weighting on smaller countries, which may receive fewer launch applications and face greater challenges in bringing innovation to patients. Measures such as harmonised packaging requirements could reduce burdens for developers, especially in the generics sector, and support a more functional single market.

Asked whether the revised general pharmaceutical legislation could help strengthen the single market, Ljoljo argued that the text provides greater predictability and addresses some security-of-supply concerns. At the same time, he stressed that further opportunities should be leveraged beyond the scope of the legislation, with a stronger focus on common European approaches.

"The challenge for Europe is not only innovation at the frontier, but also the basics: production capacity, supply chains and strengthening the single market." (Robert Ljoljo)

Closing remarks by Vytenis Andriukaitis

Vytenis Andriukaitis, Member of the European Parliament and rapporteur on the EU Biotech Act, closed the Summit by returning to the core public interest behind the pharmaceutical policy debate: accessibility, affordability and availability. He urged participants to keep the "3A" principle at the centre of reflections on pharmaceutical innovation.

Europe should choose, he suggested, value-based approaches. This means ensuring that spending is directed towards interventions that deliver measurable health value, while recognising that failure to invest in prevention and resilient supply chains can create higher costs for health systems in the long run.



He also underlined the need to demonstrate that the European model remains attractive. In this regard, the Biotech Act and wider pharmaceutical reforms were presented as opportunities to show that Europe can combine a strong industrial foundation with value-based, patient-centred health policy approaches.

"Europe should act as the Most Favourable Union in the world, joining forces to deliver on the Sustainable Development Goals, supporting humanitarian objectives and preserving social insurance systems." (Vytenis Andriukaitis)

Key takeaways

- Europe must reconcile competitiveness with affordability by rewarding meaningful, need-drive and patient-centered innovation, rather than marginal therapeutic change.
- Cooperation across regulators, HTA bodies and payers on evidence generation is welcome and needed, with real-world data used to support value-based decisions throughout the product lifecycle.
- Public payers need affordability levers, including early generic and biosimilar competition.
- Amid complex geopolitical dynamics, Europe's global position depends on a stable, coherent and predictable regulatory framework, measuring whether reforms can improve access, availability of essential supplies and health outcomes.
- Public payers should remain responsible for solidarity-based access models, without diverting limited funding to industrial policy tools nor open-ended spending commitments.

The challenge is to translate the ongoing legislative agenda into a system that supports research and innovation, ensures resilient supply across Europe and protects the affordability of healthcare for all insured people.

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