

Global pricing and HTA policy collisions and what they mean for Europe

Context and stakes for Europe

Europe's pharmaceutical market is being reshaped by forces that do not respect borders: US drug pricing reforms that increasingly reference international prices, China's fast-evolving reimbursement and procurement machinery, and Europe's own push to harmonise clinical assessment while keeping pricing and reimbursement largely national. The result is a more tightly coupled global system where an intervention in one major market can reverberate through launch sequencing, evidence standards, net-price confidentiality, and ultimately patient access.

Two baseline realities frame the challenge.

First, Europe's access problem is not primarily regulatory approval; it is the post-authorisation journey to reimbursement, procurement and uptake. EFPIA's latest W.A.I.T. data (covering new medicines approved in Europe between 2020 and 2023) shows that less than half of centrally approved innovative medicines were available to patients across the EU average, with only a minority fully reimbursed, and an average delay from approval to patient access of 578 days. [1] This "approval-to-access gap" matters because Europe is simultaneously trying to protect affordability, reduce inequities between Member States, and remain an attractive place for pharmaceutical R&D and investment.

Second, the competition for R&D, clinical trials, and first launches is intensifying. IQVIA's R&D trend analysis highlights that, while Western Europe remains a heavily utilised region for trials, its share of global "country-uses" for trials started in 2024 declined versus 2019, signalling a relative shift in activity. [2] In parallel, industry analyses argue that Europe's R&D spending growth has lagged the US and China, and that this divergence correlates with Europe's relative position in new molecular entity discovery. [3] (This view is industry-sourced and should be interpreted alongside public payer and government priorities around sustainability and opportunity cost.)

Against this backdrop, three policy arenas covered in your symposium abstract are now converging into a single strategic question for Europe: how can European systems pay for innovation (and pay for it faster and more equitably) without undermining the conditions needed to keep Europe competitive?



United States: Medicare negotiation, most-favoured-nation pricing, and trade pressure

US policy is central to Europe because the US remains the largest revenue pool for many innovative therapies—and because US reforms increasingly frame “foreign price discrimination” as a political and economic problem. When the US seeks to lower domestic prices by pointing to other high-income countries’ prices, Europe becomes both a reference point and a target.

Medicare drug price negotiation is now operational and expanding

The Medicare Drug Price Negotiation Program—created by the Inflation Reduction Act—has moved from legislation into implementation. CMS has published Maximum Fair Prices (MFPs) for an initial set of ten Medicare Part D drugs that take effect from the start of the year. [4] This is not just a US domestic change: it signals a durable federal role in price

setting for high-spend drugs, reducing the historical gap between US and non-US pricing for selected products.

The programme is also scaling. In late January 2026, CMS announced a third-cycle selection of fifteen high-cost drugs, including (for the first time) drugs payable under Medicare Part B, with negotiations occurring in 2026 and prices effective in 2028. [5] For companies, this widens the set of products exposed to federally negotiated prices and strengthens incentives to re-think US launch pricing, contracting, and lifecycle strategies—choices that often cascade into European pricing corridors.

Most-favoured-nation pricing explicitly reframes Europe as part of the problem

In May 2025, the White House issued an Executive Order focused on delivering “most-favoured-nation” prescription drug pricing to American patients. The order links potential future actions (including rulemaking planning and other measures) to whether “significant progress” toward MFN pricing is achieved, and it explicitly references enforcement activity against anti-competitive practices and broader efforts to address perceived global price discrimination. [6]

Even when MFN policies face legal, technical, or implementation constraints, the strategic implication for Europe is immediate: US political narratives increasingly treat lower European prices as evidence of “free-riding,” and this can translate into trade and diplomatic pressure for higher non-US prices or higher non-US spending on innovative medicines.

This is not theoretical. The US Trade Representative explicitly sought comments on policies and practices that allegedly force American patients to pay disproportionate costs for innovation, an institutional signal that trade policy may be used to pursue drug-pricing objectives internationally. [7]

Tariffs and supply-chain geopolitics add a second channel of spillover

Beyond pricing rules, tariffs and trade restrictions can affect Europe through costs, manufacturing location decisions, and supply resilience. In 2025, credible analyses noted the prospect of pharmaceutical tariffs in connection with a Section 232 national security investigation into imports of medicines and active pharmaceutical ingredients. [8] Reporting and policy commentary cautioned that tariff-based approaches can disrupt supply chains and increase costs, with particularly acute risks for low-margin generic supply. [9]

For Europe, the spillover is twofold: upward pressure on input costs and volatility in global supply chains, alongside the risk that “reshoring” incentives in the US attract investment away from European manufacturing unless Europe responds with its own resilience and industrial measures.



China and emerging benchmarks: value-based negotiations, procurement, and new reimbursement channels

China increasingly functions as both a scale market for innovative drugs and a global policy laboratory for cost containment through centralised negotiation and procurement. European payers and HTA bodies watch China partly because it sets expectations: on the magnitude of price concessions, the speed of access decisions, and the kinds of evidence deemed adequate for coverage.

NRDL updates and the rise of commercial reimbursement pathways

China's National Reimbursement Drug List (NRDL) is the core mechanism for defining coverage under major social health insurance schemes. In December 2025, Chinese authorities announced an updated national medical insurance drug list and the inaugural

edition of a commercial insurance innovative drug list. [10] Industry and market-access reporting indicates that these lists take effect from the start of the following year. [11]

The appearance of a formal (or semi-formal) innovative drug list linked to commercial insurance is strategically important. It suggests China is experimenting with a more layered reimbursement ecosystem: social insurance coverage pathways remain central, but commercial coverage may increasingly be used to create earlier or broader access routes for certain innovations, or to manage budget impact without abandoning innovation.

Value-based evaluation is becoming more institutionalised

Peer-reviewed analysis in the BMJ describes China's increasing use of health technology assessment in reimbursement decisions, emphasising annual NRDL adjustment and negotiated pricing as part of decision-making, while also noting ongoing challenges—especially transparency and capacity development. [12] This trajectory matters for Europe because it shows how a very large system can operationalise value assessment at scale, even if methodologies differ from European HTA traditions.

Volume-based procurement changes the reference frame for “reasonable” prices

China's national volume-based procurement (NVBP) programme centralises purchasing power to drive price reductions and expand access. Detailed analysis in BMJ Global Health characterises NVBP as pooled procurement designed to reduce prices, enhance affordability and access, and reshape market functioning. [13]

For Europe, China's procurement environment matters in at least three ways:

- 1) It influences global pricing benchmarks and internal company “floor pricing” assumptions for high-volume categories.
- 2) It creates incentives for China-based manufacturers to scale rapidly, affecting global competition (including in biosimilars and some innovative modalities).
- 3) It reinforces the global move toward evidence-plus-contracting models, where reimbursement is tightly linked to budget impact management and real-world performance monitoring.



Europe: HTA harmonisation, real-world evidence infrastructure, and regulatory reform

Europe’s response to global pressures has three main pillars: harmonising clinical assessment (HTA), building data and real-world evidence capacity, and updating pharmaceutical legislation to address access inequities, innovation incentives, and supply resilience.

Joint Clinical Assessment is now a structural feature of European market access

The EU Health Technology Assessment Regulation sets out a phased introduction of EU-level Joint Clinical Assessments (JCAs) for medicinal products. The regulation specifies that, from mid-January 2025, JCA applies to new active substances for cancer indications and to advanced therapy medicinal products, with expansion to orphan medicinal products in early 2028 and to other medicinal products in early 2030. [14]

Strategically, this changes the European evidence game in two crucial ways:

- The centre of gravity for “clinical value demonstration” shifts toward an EU-level assessment process, increasing the importance of getting the comparative clinical narrative right once, for many Member States.
- National processes remain decisive for price and reimbursement, but the clinical assessment layer becomes more standardised—raising the premium on early alignment around comparators and endpoints that will be accepted across systems.

Joint Scientific Consultations (JSCs) are designed as an upstream tool: they allow developers to seek EU-level scientific consultation on evidence needs for a future JCA during planning of clinical studies. [15] For manufacturers, this creates a new “early advice” node that can reduce downstream misalignment—if used strategically.

Real-world evidence capacity is moving from aspiration to infrastructure

Europe’s real-world evidence agenda is increasingly institutionalised through regulator-led networks and broader data policy.

DARWIN EU, established by EMA and the European medicines regulatory network, is designed to provide timely and reliable evidence on use, safety, and effectiveness of medicines from real-world healthcare databases across the EU. [16] This matters to market access because payers and HTA bodies are increasingly demanding evidence not only of efficacy (in trials) but of effectiveness and budget impact in routine care—especially for high-cost, high-uncertainty therapies.

At the same time, EU data governance is changing. The European Health Data Space is now enacted as Regulation (EU) 2025/327, adopted in February 2025 and published in March 2025. [17] The regulation’s purpose explicitly includes enabling secondary uses of electronic health data for research, innovation, policymaking, and regulatory activities. [18] Over time, EHDS should expand the feasible set of RWE studies in Europe—but it also raises new compliance, governance, and trust questions that will shape how quickly these benefits materialise in HTA and payer decision-making.



Policy milestones timeline

Marker	Region	Date	Milestone	Why it matters for Europe
1	EU	January 2025	JCA starts for oncology and ATMP new active	EU-level clinical value framing becomes more central to

Marker	Region	Date	Milestone	Why it matters for Europe
			substances [14]	access strategy
2	EU	February 2025	EHDS adopted [17]	Legal foundation for broader secondary use of health data
3	EU	March 2025	EHDS published in the Official Journal [17]	Triggers transition toward application across obligations
4	US	May 2025	MFN Executive Order issued [6]	Increases pressure on “low-price” countries and ties pricing to trade narratives
5	China	December 2025	NRDL update plus first commercial innovative drug list announced [10]	Signals multi-channel coverage experimentation; may influence global benchmarks
6	EU	December 2025	Council and Parliament reach a deal on the “pharma package” [19]	Major change in access, competitiveness, and supply framework (details finalised thereafter)
7	US	January 2026	Initial Medicare MFPs take effect for ten Part D drugs [4]	Federal price setting becomes real, affecting global pricing corridors
8	China	January 2026	NRDL and commercial list reported to take effect [20]	Expands operational reality of layered reimbursement
9	US	January 2026	CMS selects drugs for third negotiation cycle (including first Part B drugs) [5]	Wider product exposure; increases long-term significance of negotiation
10	EU	January 2028	Orphan medicines enter JCA scope [14]	Orphan evidence and value standards become more pan-European
11	EU	January 2030	Remaining medicinal products enter JCA scope [14]	JCA becomes the default EU clinical assessment pathway for new medicines

Pharmaceutical law reform and supply resilience are now explicit competitiveness tools

Europe’s broader pharmaceutical framework is also changing. In December 2025, the Council and the European Parliament reached an agreement on a new “pharma package,” described by EU institutions as a far-reaching reform intended to increase access to medicines and make the sector fairer and more competitive, while reducing regulatory burdens and strengthening security of supply to prevent and manage shortages. [19] EMA

likewise signalled that this was a major overhaul, with details to be fully elaborated after the political agreement. [21]

In parallel, the EU proposed a Critical Medicines Act in March 2025 designed to improve availability, supply, and production of critical medicines within the EU, explicitly motivated by shortages and geopolitical vulnerability. [22] The policy direction is clear: Europe is treating medicine security not only as a health issue but as an element of strategic autonomy.

Where policies converge and diverge

The most important insight for a market-access audience is that convergence is happening on *questions* (what payers ask), even when there is divergence on *instruments* (how payers act).

Convergence: value, evidence, and budget impact discipline

Across the US, China, and Europe, decision-makers are converging on a shared set of demands: clear comparative clinical benefit, credible evidence for real-world performance, and mechanisms to manage budget impact for high-cost therapies.

- In the US, Medicare negotiation institutionalises budget impact discipline and formalised price setting for selected high-spend drugs. [23]
- In China, annual NRDL negotiations and NVBP pooled procurement are designed to translate value and scale into lower prices and broader access. [24]
- In Europe, JCA creates a shared clinical assessment layer, while data infrastructures (DARWIN EU, EHDS) aim to make RWE more usable for lifecycle decisions. [25]

A practical implication: manufacturers can no longer treat RWE as an optional “post-launch nice-to-have.” Europe’s move toward EU-level clinical assessment plus stronger RWE tools increases the likelihood that post-authorisation evidence will influence not just reassessment but also initial reimbursement conditions and contracting terms.

Divergence: the politics of “fairness” and the geopolitics of pricing

Where divergence is sharpest is in how pricing is justified politically.

- The US MFN narrative frames international price differentials as unfair “free-riding” and ties remedies to executive action, enforcement, and potentially trade mechanisms. [26]
- Europe frames fairness primarily as intra-European equity (reducing access gaps between Member States), sustainability of health budgets, and security of supply. [27]

- China frames fairness and sustainability largely through system-level affordability and the use of state purchasing power to secure lower prices and wide coverage. [\[28\]](#)

These differences matter because they create collision points. For example, Europe's use of lower prices to protect affordability strengthens the US argument for MFN, which may in turn increase pressure on Europe to raise prices or spending—potentially undermining European affordability goals and increasing political risk for European payers.



Implications and strategic actions for market access leaders

This policy environment rewards organisations—both companies and policymakers—that can manage “multi-system alignment”: evidence, price, and access strategies designed for spillovers, not silos.

For pharmaceutical companies: build an integrated evidence and pricing architecture

A Europe-facing access strategy now needs to be designed with at least four realities in mind:

EU-level clinical assessment will shape the narrative. With JCA phased in across major categories of medicines through the end of the decade, companies should treat “EU comparators and endpoints” as foundational, not local adaptations. [14] The scoping dynamics and early advice mechanisms (e.g., Joint Scientific Consultations) are key levers to reduce downstream surprises. [15]

RWE is becoming a licence-to-operate capability. DARWIN EU’s purpose is explicitly to generate real-world evidence that EU regulators can use across the lifecycle of a medicine. [16] EHDS, as enacted law, signals that secondary use of health data is a strategic EU priority for research, innovation, and regulatory activity. [29] A robust European RWE plan—data access, governance, study protocols, and stakeholder trust—should now be part of launch preparedness.

Pricing corridor management is harder under MFN politics. Even if MFN implementation remains uncertain in practice, the US political direction increases the risk that European list prices (and sometimes net prices, if leaked or inferred) become an input into US price demands. [26] This strengthens the business case for disciplined global price governance, scenario planning for trade-related shocks, and careful handling of reference baskets.

Contracting will increasingly be the bridge between uncertainty and access. Managed entry agreements (financial and outcomes-based) remain a key tool for payers to manage uncertainty and budget impact, particularly for high-cost medicines with immature evidence at launch. [30] The growing institutional emphasis on RWE increases the feasibility—and the scrutiny—of outcomes-based arrangements.

For European policymakers: align speed and equity with credibility and competitiveness

Europe’s policy challenge is to ensure that new EU-level structures actually reduce delay and duplication, rather than adding an additional layer of process.

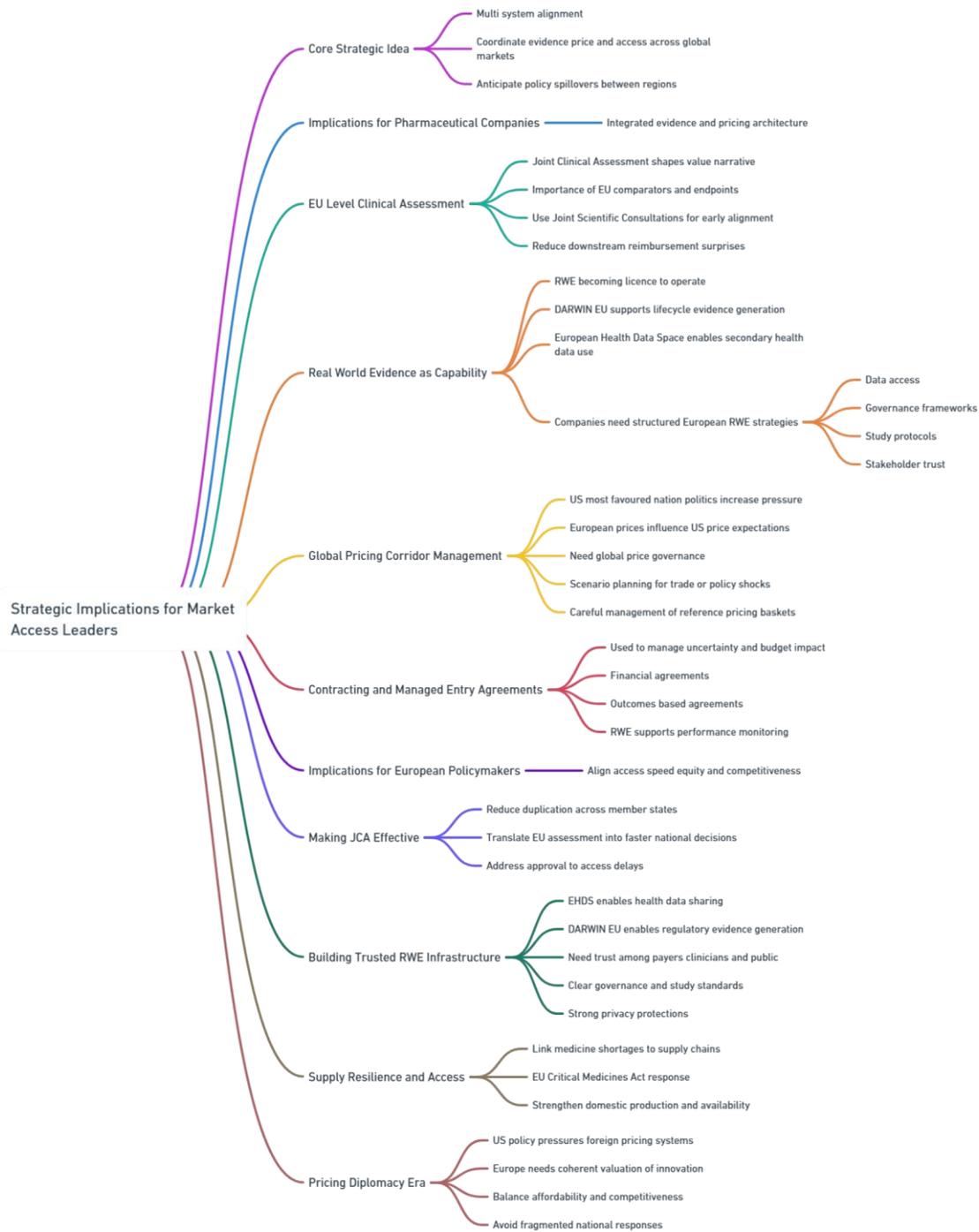
Make JCA a time-saver, not a time-cost. EFPIA’s access metrics show long post-authorisation delays and significant variation across Member States. [1] If JCA does not translate into faster national decisions, Europe risks building a technically elegant system that does not solve the lived access problem.

Invest in trusted, interoperable data pathways for RWE. EHDS creates a legal framework for broader use and exchange of health data; DARWIN EU provides a regulatory network capability for real-world interrogation. [31] But RWE only improves access outcomes if it is trusted by payers, HTA bodies, clinicians, and the public. That requires governance clarity,

transparent study standards, and an operational approach to privacy and trade-secret concerns.

Treat supply resilience as part of access, not only industrial policy. The EU's Critical Medicines Act proposal explicitly links shortages to manufacturing and supply-chain vulnerabilities and seeks to strengthen the availability and production of critical medicines within the EU. [22] In a world of tariff threats and geopolitical shocks, resilience measures can protect both patients and negotiating leverage.

Prepare for a pricing diplomacy era. US policy increasingly links domestic affordability to foreign pricing behaviour. [26] Europe will need a coherent stance on how it values innovation, how it sets prices, and how it defends affordability—while avoiding fragmented national responses that increase inequity and weaken Europe's position in trade negotiations.



[1] [27] New data shows no shift in access to medicines for millions of Europeans

<https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/new-data-shows-no-shift-in-access-to-medicines-for-millions-of-europeans/>

[2] Global Trends in R&D 2025 | IQVIA

<https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-trends-in-r-and-d-2025>

[3] Despite a decade of gradual growth, R&D spending in Europe outpaced by the US – with increasing competition from China, new data shows

<https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/despite-a-decade-of-gradual-growth-rd-spending-in-europe-outpaced-by-the-us-with-increasing-competition-from-china-new-data-shows/>

[4] [23] Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026 | CMS

<https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026>

[5] CMS Announces Selection of Drugs for Third Cycle of Medicare Drug Price Negotiation Program, Including First-Ever Part B Drugs | CMS

<https://www.cms.gov/newsroom/press-releases/cms-announces-selection-drugs-third-cycle-medicare-drug-price-negotiation-program-including-first>

[6] [26] Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients – The White House

<https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/>

[7] USTR Seeks Comments Regarding Foreign Nations Freeloading on American ...

https://ustr.gov/about/policy-offices/press-office/press-releases/2025/may/ustr-seeks-comments-regarding-foreign-nations-freeloading-american-financed-innovation?utm_source=chatgpt.com

[8] How Pharmaceutical Tariffs Will Affect US Health Care Costs

https://aei.org/wp-content/uploads/2025/09/How-Pharmaceutical-Tariffs-Will-Affect-US-Health-Care-Costs.pdf?x85095=&utm_source=chatgpt.com

[9] Trump plans a hefty tax on imported drugs, risking higher prices and shortages

https://apnews.com/article/8e8a78b699c8dbe728140ae0815b001c?utm_source=chatgpt.com

[10] China updates national medical insurance catalog, adds 114 new drugs

https://english.www.gov.cn/news/202512/07/content_WS6934f5f6c6d00ca5f9a07f64.html

[11] [20] China releases 2025 NRDL and first commercial insurance drug list

https://www.pharmaceutical-technology.com/pricing-and-market-access/china-2025-nrdl-first-commercial-insurance-drug-list/?utm_source=chatgpt.com

[12] [24] Use of health technology assessment in drug reimbursement ... - The BMJ

https://www.bmj.com/content/381/bmj-2021-068915?utm_source=chatgpt.com

[13] [28] Improving access to medicines and beyond: the national volume-based ...

https://gh.bmj.com/content/bmjgh/8/7/e011535.full.pdf?utm_source=chatgpt.com

[14] [25] Regulation - 2021/2282 - EN - EUR-Lex

<https://eur-lex.europa.eu/eli/reg/2021/2282/oj/eng>

[15] Joint Scientific Consultations - Public Health - European Commission

https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-scientific-consultations_en?utm_source=chatgpt.com

[16] Home

<https://darwin-eu.org/>

[17] [29] [31] Regulation - EU - 2025/327 - EN - EUR-Lex

<https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng>

[18] Regulation - EU - 2025/327 - EN - EUR-Lex

https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng?utm_source=chatgpt.com

[19] 'Pharma package': Council and Parliament reach a deal on new rules for a fairer and more competitive EU pharmaceutical sector - Consilium

<https://www.consilium.europa.eu/en/press/press-releases/2025/12/11/pharma-package-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>

[21] Reform of the EU pharmaceutical legislation

https://www.ema.europa.eu/en/about-us/what-we-do/reform-eu-pharmaceutical-legislation?utm_source=chatgpt.com

[22] Critical medicines Act - Public Health - European Commission

https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/critical-medicines-act_en?utm_source=chatgpt.com

[30] HPR46 Exploring Managed Entry Agreements: A Scoping Review of ...

https://www.valueinhealthjournal.com/article/S1098-3015%2824%2904336-5/fulltext?utm_source=chatgpt.com