

From Cost Containment To Modernization: Market Access Updates Across The EU4 And The UK In 2025

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Background and Objective

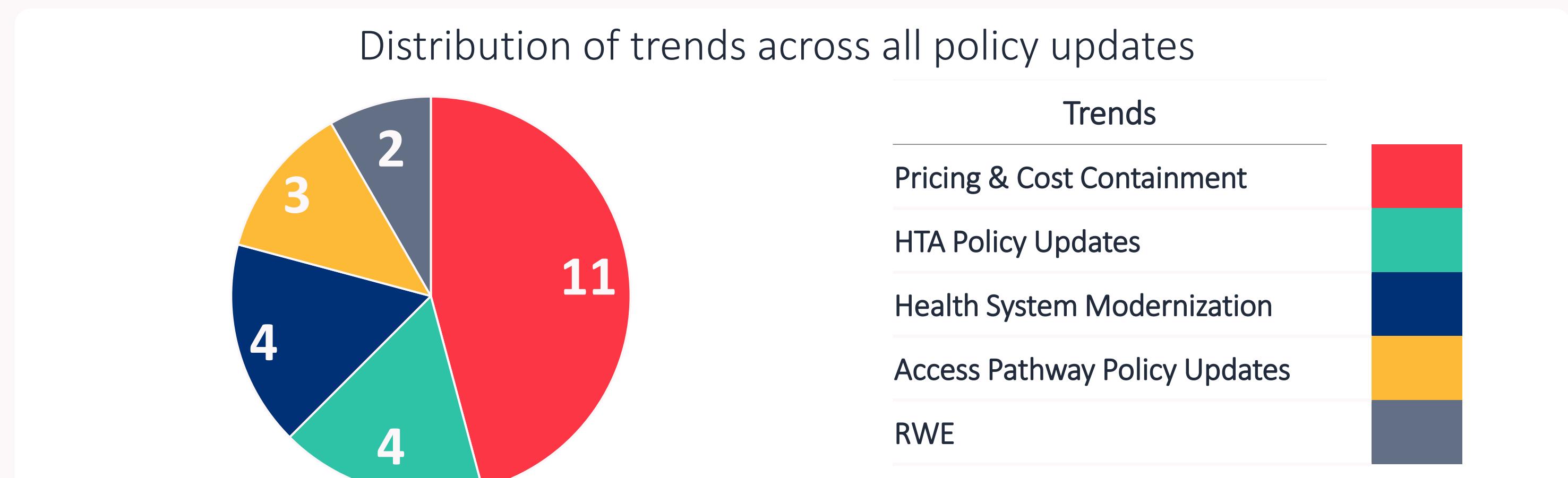
- In 2025, European countries are implementing a considerable number of policy reforms to manage national healthcare system (NHS) expenditures, optimize access pathways, and update NHS services.
- This research systematically maps these changes across the EU4 and the UK, assessing their implications for pharmaceutical launch strategies and patient access.

Results

- A total of 24 new policies were identified across the UK (n=7), France (n=5), Germany (n=3), Italy (n=3) and Spain (n=3).
- The most prominent trend detected was Pricing & Cost Containment (45.8%), followed by NHS Service Modernization (16.7%) and HTA Processes (16.7%), Access Pathway Updates (12.5%), and RWE (8.3%).
- Germany's focus is overwhelmingly on pricing, with removal of IRP and confidential pricing policy. Similarly, also the UK and France primarily focus on pricing and cost-containment with nearly half of their policy updates centred on this. In addition, the UK is geared towards Access Pathway updates and RWE.
- Spain is streamlining national HTA process and improving NHS coordination and response capacity.
- Italy shows equal distribution across trends as it undergoes changing in AIFA's innovativeness criteria and updates spending limits.

Methods

- A structured review of publicly available national policy updates (issued between 01/01/2025 and 15/10/2025) was conducted across 5 major European markets: the UK, France, Germany, Italy, and Spain.
- Identified policies were categorized into 5 trends: Pricing & Cost Containment, HTA & Evaluation Policy Updates, Access Pathway Updates, Health System Modernization, Access Pathway Policy Updates, and RWE. Trends and policies are not mutually exclusive to reflect their multidimensional impact.



Policy updates across the EU4 and the UK

	Detail	Trend		Detail	Trend
ILAP relaunch	More selective entry but with a simpler roadmap, prioritised support, and deeper NHS involvement; streamlining early engagement across regulators, HTA, and the NHS to speed access to transformative therapies ¹⁻²	Yellow	Ending IRP	MRA eliminates IRP by removing the obligation to report EU sales prices reducing external price benchmarking ¹¹⁻¹³	Red
HST updates	It refines eligibility for ultra-rare diseases to improve transparency and prioritize therapies addressing the highest unmet need ³	Yellow	DRG update	DRG become hybrid: 60% of costs are guaranteed as provision budget to maintain quality of hospital services and structures, 40% tied to treatment cases, curbing incentives that maximize case volumes ¹⁴	Red
MHRA-NICE joint service	Parallel MHRA-NICE decision making over licensing and value at the same time, accelerating patient access by up to six months ⁴	Green	Confidential pricing	DRG reform also modernizes hospital financing, shifting from activity-based to a hybrid embedding structural funding and quality criteria ¹¹⁻¹²	Blue
Statutory Scheme	The revision introduces tiered payment rates for newer and older medicines, a top-up mechanism, and expanded exemptions, aiming at NHS cost control while supporting commercial sustainability for manufacturers ⁵⁻⁶	Red	MRA introduces confidential discounts, but restrictive eligibility, a 9% mandatory discount, and heavy bureaucracy may limit uptake ^{11;15}	Red	
VPAG increase	It introduces a sharp rise in payback rates up to 35.6%, with no agreement yet reached between manufacturers and government over its revision ⁷	Red	Innovative status updates	Innovative status is limited to serious diseases with medium-to-low epidemiological impact; conditional innovativeness phased out, and medicines with moderate added therapeutic value and moderate evidence can qualify ¹⁶	Yellow
BI Threshold increase	NHS England doubles the BI test threshold from £20m to £40m, reducing the number of drugs triggering additional pricing negotiations to streamline access while still managing costs ⁸⁻⁹	Red	Budget Law	Integration of economic evaluation, reinforcing AIFA's efforts to link added therapeutic value with CE	Blue
RWE Pilot	MHRA's pilot to harmonise RWE standards and align regulatory and HTA expectations, supporting robust evidence generation for UK evaluations ⁹	Grey	LEA updates	Caps funds for innovative (€900M) and conditionally innovative (€300M) drugs, and antibiotics for AMR (€100M), reinforcing spending limits while prioritizing high-need areas ¹⁷	Red
Efficiency Agreement	A Government and pharmaceutical industry agreement on a €600M savings plan focused on efficient drug use and best practices, targeting spending efficiency and predictability, including a safeguard clause cap of €1.6B ²¹	Red	HTA Royal Decree*	Adds lifecycle evaluations of marketed drugs, clarifies rules for inclusion, exclusion, and review in public funding ¹⁹⁻²⁰	Red
Commercial discount cap	20% annual limit on rebates and discounts for generics and reference drugs priced like generics, promoting generic dispensing and containing public drug expenditure. ²²	Red	Law on Medicines and Health Products	Centralizes assessments, increases regional and stakeholder involvement, and aligns the HTA with EU JCA, for more transparency and efficiency ¹⁹⁻²⁰	Green
S2E (HE)	New service under HAS leading economic evaluations, for a more rigorous cost-effectiveness assessments ²³	Green	AESAP creation	Reforms the reference price system that sets a funded price range and allows a biannual price offering from companies to foster competition, diversify supply but still strengthening cost control ¹⁹⁻²⁰	Red
Modernization Pact	Government-industry partnership to enhance domestic manufacturing, accelerate innovation uptake, and modernize system governance ²¹	Blue		The creation of AESAP is a structural reform to improve Spain's public health response capacity and coordination following the COVID experience ¹⁹⁻²⁰	Blue
SNDS data pilot use	Pilot use of SNDS' RWE data to monitor early access patients, easing provider burden and strengthening real-world evidence ²⁴	Grey			

Conclusions

- 2025 reflects an evolving policy landscape characterized by continued focus on pricing reforms, access pathways, and the integration of RWE. Policies are driving stronger integration of RWE in treatment effectiveness assessments, advancing value-based frameworks, and raising the standards for what constitutes value. Manufacturers should respond by adopting adaptive launch strategies that prioritize earlier evidence generation planning to support robust value demonstration and ensure alignment with national access priorities.

Abbreviations

AESAP – Agencia Española de Servicios y Acceso a Pacientes (Spanish agency for services and patient access); AIFA – Agenzia Italiana del Farmaco (Italian Medicines Agency); AMR – Antimicrobial Resistance; ABPI – Association of the British Pharmaceutical Industry; BI – Budget Impact; BMG – Bundesministerium für Gesundheit (German Federal Ministry of Health); CE – Cost Effectiveness; DSHC – Department of Health and Social Care; DRG – Diagnosis-Related Group; EU JCA – European Union Joint Clinical Assessment; EU4 – European Union Four (France, Germany, Italy, Spain); HAS – Haute Autorité de Santé (French National Health Authority); HST – Highly Specialised Technologies; HTA – Health Technology Assessment; ILAP – Innovative Licensing and Access Pathway; IRP – International Reference Pricing; LEA – Essential Levels of Care; MEF – Ministère de l'Économie et des Finances (French Ministry of Economy and Finance); MHRA – Medicines and Healthcare products Regulatory Agency; MRA – Medicines Research Act; MS – Ministerio de Sanidad (Spanish Ministry of Health); MSP – Ministère de la Santé et de la Prévention (French Ministry of Health and Prevention); NBS – Newborn Screening; NHS – National Health Service; NICE – National Institute for Health and Care Excellence; RWE – Real-World Evidence; S2E (HE) – Service to Establish (Health Economics); SNDS – National Health Data System; VPAG – Voluntary Pricing and Access Scheme

Notes

*Royal Decree still under final review (as of October 2025)

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