NAVLIN
BY EVERSANA™

INSIGHTS Newsletter

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As U.S. MFN Policy Takes Shape, Global Markets Begin to Respond

Over the past month, more details around the U.S. government's approach to Most Favored Nation (MFN) drug pricing have fallen into place, with President Donald Trump leaning into voluntary deals with pharmaceutical companies and continuing to wield tariff threats as leverage.

FDA Announces National Priority Voucher Recipients

The U.S. Food and Drug Administration (FDA) has unveiled the first recipients of its new Commissioner's National Priority Voucher (CNPV) pilot program. Designed to fast-track drug reviews for products that align with U.S. national interests, the program reduces FDA review timelines from nearly a year to as little as one month.

Innovative Drug Pricing Models Across Europe & Beyond

In last month's newsletter, we covered the alternative reimbursement pathways adopted across the EU5 countries to improve patient access and manage budgetary constraints. Building on that discussion, this month's edition delves into alternative pricing and payment models being implemented across Europe and other regions.

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NAVLIN DAILY
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Editor's Note

This month we've been mostly tracking the spiders web that is MFN. What's going on in the U.S.? What impact will it have on Europe or APAC? How are companies feeling or responding to the policy?

You can read all about it in this month's newsletter but if your company is following MFN closely and wants to stay up-to-date on the latest developments, ask us about NAVLIN's MFN tracker. We're watching out for price changes, company strategies, launch tactics and senior leadership commentary (among other things) around MFN that could help you stay ahead, delivered weekly in a syndicated report.

As for upcoming events, ISPOR Europe next! Hopefully see everyone in Glasgow, don't hesitate to come say Hi and pepper us with any market access-related questions you may have. Or where to eat the best haggis in Glasgow! We can try and help, at least.

Enjoy,

Anna Smith

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NAVLIN Insight: As U.S. MFN Policy Takes Shape, Global Markets Begin to Respond

Raechel Pusateri

NAVLIN BRIEF:

- Over the past month, more details around the U.S. government's approach to Most Favored Nation (MFN) drug pricing have fallen into place, with President Donald Trump leaning into voluntary deals with pharmaceutical companies and continuing to wield tariff threats as leverage
- Although initial reactions to the drug pricing deals struck by President Trump suggest that industry views the arrangements positively, it is challenging to evaluate the true impact of the agreements without further details. Additionally, the threat of rulemaking remains if no "significant progress" is made toward implementing MFN voluntarily
- Meanwhile, in other markets, some government entities are responding to the risk of MFN by warning about the possibility of delayed or skipped drug launches

THE DETAILS

WASHINGTON, DC, United States—So far, the Trump administration has announced individual Most Favored Nation (MFN) agreements with three pharmaceutical companies to align their prices with MFN: Pfizer, AstraZeneca, and EMD Serono.

All three deals are voluntary and built around the same core framework. In exchange for exemptions from Section 232 tariffs, companies must offer MFN pricing in Medicaid; promise to set prices on new drugs launched in the U.S. at no more than prices in other wealthy countries; commit to investing in U.S. manufacturing and research; and make certain drugs available through the Trump administration's new direct-to-patient (DTP) model, TrumpRx.

Without Additional Information, Impact of Deals in U.S. Appears Limited

Although the deals have been revealed with much fanfare, the early stock market response suggests that investors view the voluntary arrangements as a win for the pharmaceutical industry and anticipate little impact on revenue.

Medicaid, which covers low-income patients, already receives substantial discounts from drugmakers through a mix of federal and state policies, including the Medicaid Drug Rebate Program. The low prices already paid by Medicaid for many brand-name products suggest that the adoption of MFN pricing within the program could be less significant than headlines imply.

There are also uncertainties about the scope of products that will be offered through Medicaid, as well as the administration's methodology for arriving at MFN prices. Additionally, the net prices paid by Medicaid are confidential, as are the net prices paid by the governments of other countries to manufacturers, making it challenging to compare discounts and determine the full impact of the deals on program spending.

TrumpRx is also expected to be less disruptive than advertised. Although DTP platforms have the potential to make some medications more affordable for a subset of cash-paying patients with inadequate insurance coverage, the price of many high-cost and specialty drugs will likely remain out of reach for many patients. Additionally, payments made through DTP channels do not currently count toward a patient's health insurance deductible or out-of-pocket maximum, further disincentivizing the use of DTP arrangements.

Overall, the way that current DTP models are structured does not allow them to bypass traditional access channels facilitated by middlemen like pharmacy benefit managers (PBMs) and insurance providers. Instead, they simply serve as another option that caters mostly to patients who lack insurance coverage of certain medications.

If patients can use insurance on TrumpRx, the service could prove more impactful than existing DTP options. However, few details on TrumpRx have been released, and initial reports suggest that the site will likely serve as a central repository to connect patients to manufacturer-run DTP platforms rather than fundamentally change the existing model.

How is MFN Affecting Other Markets?

Under the voluntary pricing agreements, Pfizer, AstraZeneca, and EMD Serono have also committed to

not launching new drugs at a higher price in the U.S. than in other, similarly wealthy countries. There is no cap on the launch price overall, and the Trump administration's emphasis on "equalizing" the prices paid for drugs in the U.S. with prices paid in other countries could have the effect of raising prices abroad rather than significantly lowering them in the U.S.

Already, some pharmaceutical companies have made headlines by increasing the list price of their medications in other countries to match list prices in the U.S. Bristol Myers Squibb (BMS) announced that it would launch Cobenfy (xanomeline and trospium chloride) in Britain at a price matching its U.S. list price. Soon after, AbbVie said it would match the UK launch price of its ovarian cancer treatment Elahere (mirvetuximab soravtansine) to its U.S. list price.

Eli Lilly, similarly, made a recent decision to increase Mounjaro (tirzepatide) prices in the UK, a decision now confirmed to be driven by the push for MFN pricing in the U.S.

Questions remain about whether increased list prices abroad will impact final prices after confidential discounts and rebates. Other governments have so far pushed back against the idea of paying more for branded drugs and are unlikely to easily concede to higher prices to offset discounts in the U.S.

Still, several countries—especially those in the APAC region—have begin to voice concerns over the impact of U.S. drug pricing policies like MFN and tariffs. Depending on the policy's scope and implementation, MFN could significantly reshape launch strategies in referenced markets. To avoid MFN pricing in the U.S., companies could delay or skip markets with lower list prices that are included in the reference basket for MFN.

Medicines Australia recently published a statement suggesting that drugmakers are already delaying or skipping launches in the country due to MFN. "We are already seeing the impact of these policies, with a slow-down in new medicines coming to Australia. Our members are advising that there is significant scrutiny over new medicines launches, by their international headquarters, due to low prices in Australia. They are choosing not to launch new medicines here, or to delay medicines launches." However, the group did not provide specific examples or data to support its claims.

A recent EFPIA Japan survey found that four out of the ten companies included in the questionnaire have seen impacts on products in Japan due to MFN. All 10 companies surveyed by EFPIA Japan responded that they believe MFN will impact their global pricing strategy. Seven of the 10 noted that products had already been affected in other countries, and four confirmed that their products in Japan had been directly affected.

Local media reports claim that multinational companies are already delaying Korean regulatory approval or reimbursement listing for select products because they fear that Korean prices could weigh down the maximum U.S. price allowed under the MFN policy. Specifically, lupus drugs and AstraZeneca's breast cancer drug Faslodex (fulvestrant) have been withdrawn from the Korean market.

Germany is also preparing for the potential impact of MFN on pricing in Europe. In a recent interview with Handelsblatt, David Fredrickson, Head of Oncology at AstraZeneca (AZ), commented, "We need to talk about better financing and pricing – measured against a country's economic strength. Pharmaceutical companies will invest in countries where innovation is rewarded and patients have faster access to new therapies."

The interview was published shortly after Fredrickson discussed the pharmaceutical industry and drug prices with the Chancellor's Office and Health Minister Nina Warken (CDU). He highlighted: "The fact that this exchange took place so soon after the U.S. agreement shows how seriously the German government is taking this issue."

What's Next?

Other drugmakers are expected to announce agreements with the White House in the coming weeks. At the end of July, the White House sent letters to 17 pharmaceutical manufacturers demanding "decisive action" on MFN drug pricing within 60 days.

Remaining companies from that list include AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Genentech, Gilead, GSK, Johnson & Johnson, Merck, Novartis, Novo Nordisk, Regeneron, and Sanofi.

The Trump administration has also threatened to take additional steps like rulemaking if no "significant progress" is made toward implementing MFN voluntarily. Two potential rules are currently under review at the Office of Management and Budget (OMB), including one called the "Global Benchmark for Efficient Drug Pricing (GLOBE) Model" (submitted September 25) and another called the "Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model" (submitted October 2).

Generally, the website of the Office of Information and Regulatory Affairs (OIRA) has 90 days to review proposed rules; however, this timeline is likely to be delayed by the U.S. government shutdown. No additional details about the models have been made public.

According to Reuters, who spoke to two pharmaceutical lobbyists familiar with the matter, drugmakers expect the GLOBE Model to mirror a 2020 proposal the first Trump administration tried to implement.

The 2020 rule, which was rescinded by the Biden administration following a court-ordered injunction, would have tested paying for drugs covered under Medicare Part B at comparable amounts to the lowest adjusted price paid by any country in the Organization for Economic Co-operation and Development (OECD) whose gross domestic product is comparable to the United States. Initially, the model focused on a set of 50 separately payable Medicare Part B drugs that encompass a high percentage of Medicare Part B drug spending.

NAVLIN Insight: Innovative Drug Pricing Models Across Europe & Beyond

Rajdeep Dey

NAVLIN BRIEF:

- In last month's newsletter, we covered the alternative reimbursement pathways adopted across the EU5 countries to improve patient access and manage budgetary constraints. Building on that discussion, this month's edition delves into alternative pricing and payment models being implemented across Europe and other regions
- Over the past few years, the rapid increase in drug prices and the complex, shifting nature of treatment lines have made traditional pricing frameworks less effective. This has led to a growing emphasis on innovative payment mechanisms, such as outcome-based agreements, risk-sharing models, and instalment-based pricing
- Alternative pricing and payment models can help mitigate major challenges in healthcare financing, including uncertainty about long-term treatment outcomes, affordability concerns, and budgetary pressures. By linking reimbursement to actual patient outcomes and spreading financial risk more equitably, these approaches aim to ensure faster and fairer access to high-cost innovative therapies for patients across diverse healthcare systems

THE DETAILS

BRUSSELS, Belgium—Traditional pricing and reimbursement models often relying on arbitrary rebates, simple price-volume agreements, and budget caps which can act as barriers to timely patient access. To address these challenges, payers and policymakers are experimenting with novel pricing and payment models. These mechanisms are dynamic and evolving, designed to balance affordability with innovation while reducing uncertainty about real-world effectiveness.

Indication & Combination-based Pricing

One group of approaches focuses on "indication- and combination-based pricing." Indication-based pricing recognises that a single medicine may offer different levels of value across multiple indications and sets prices accordingly. Combination-based pricing seeks to resolve the complexity of valuing medicines used together, particularly when multiple manufacturers are involved, ensuring that value reflects the treatment's combined benefit rather than the sum of its parts.

Outcomes-based Payments

Another category includes "outcomes-based payments", where reimbursement is tied directly to real-world clinical performance. Such models are useful when there is uncertainty around durability of benefits at launch. A notable mechanism here is coverage with evidence development, which grants access on the condition that further data are collected within a specified timeframe.

Over-time or Staggered Payments

This category allows payers to spread the cost of high-priced one-time therapies across several years. When linked to outcomes, these staggered payments are only continued if therapeutic benefit is confirmed.

Subscription or Lump-sum Payments

Finally, "subscription or lump-sum payments" are being tested in some countries, where payers provide a fixed annual or multi-year fee for unlimited use of a medicine, enabling greater predictability of budget impact.

Various countries are adopting alternative pricing and payment models:

Italy has developed one of the structured approaches in Europe for managed entry agreements tied with innovative pricing models administered through the Italian Medicines Agency's (AIFA) national registry system. These agreements are divided into two main categories: outcome-based and financial-based models.

Outcome-based agreements include risk-sharing, payment-by-result, payment-at-result, and success-fee arrangements, all of which tie reimbursement to the level of clinical benefit achieved by patients.

Financial-based schemes focus on budget control and include cost-sharing, where manufacturers refund part of the cost for each treated patient regardless of outcome, and capping mechanisms, which establish expenditure thresholds beyond which companies must reimburse payers.

The overall impact is considerable. Reimbursements under managed entry agreements total EUR 213 million, representing roughly 1% of National Health Service (SSN) spending. Between 2020 and 2022, AIFA's registry system recorded a broad mix of agreements. In 2022, financial agreements made up 83% of total reimbursements (around EUR 67 million), with 67% from cost-sharing

and 16% from capping. Outcome-based agreements accounted for 17% of refunds, though the contribution of risk-sharing was marginal (<0.01%) due to administrative complexities.

In addition to registries, AIFA applies expenditure ceilings by product and price/volume agreements. These mechanisms are designed to encourage appropriate use of medicines while limiting SSN expenditure. Expenditure ceilings are generally applied in the first 12–24 months after a product enters the market, with excess spending triggering company paybacks that are redistributed to regions. Price/volume agreements apply progressive discounts as product sales increase. These may either reduce official prices or result in reimbursements to specific regions, depending on contractual terms.

AIFA can also negotiate confidential discounts directly with pharmaceutical companies. These do not generate regional paybacks but instead reduce invoice prices to SSN healthcare facilities. Confidentiality applies only to the scale of the discount, not the existence of the agreement.

In the United Kingdom, managed access agreements combined with financial models are widely used to provide time-limited access to promising new treatments while additional evidence is collected.

Recently, the National Institute for Health and Care Excellence (NICE) revealed that its recommendation of CSL Behring's Hemgenix (etranacogene dezaparvovec) forms part of the first pilot for outcome-based agreements (OBAs) under the 2024 Voluntary Scheme for Pricing, Access, and Growth (VPAG).

At ISPOR Europe 2024, David Thomson, MSc, of the National Institute for Health and Care Excellence (NICE), discussed the role of Outcome-Based Risk Sharing Agreements in England, noting that outcome-based or leasing-style agreements are regaining prominence after a period in which finance-based schemes were favored. He pointed to pilot Outcome-Based Agreement for Hemgenix, and added that the pilot is designed to assess the feasibility, administrative burden, and overall effectiveness of outcome-based pricing models in practice.

A notable earlier example of innovative pricing was the UK's 2022 antimicrobial "subscription-style payment model," designed to combat antimicrobial resistance (AMR). Through this arrangement, the NHS provided access to Shionogi's Fetcroja (cefiderocol) and Pfizer's Zavicefta (ceftazidime/avibactam). Under this subscription-style payment model, companies receive a fixed annual payment based on the assessed value of their medicines to the NHS, rather than the volume of use.

NICE was the first HTA agency globally to estimate the full value of antimicrobials using health technology assessment methods. These appraisals informed commercial negotiations between NHS England, NHS Improvement, and the manufacturers. Under the agreement, Shionogi received a fixed £10 million annual payment, reflecting the value of its drug to the NHS, rather than sales volume.

This year, in Germany CSL Behring treated the first patient with CSL Behring's Hemgenix (etranacogene dezaparvovec), a gene therapy for haemophilia B. The company and the GKV-Spitzenverband reached an agreement on a national "success-based reimbursement model" marking a milestone as the first gene therapy approved in Europe for haemophilia B to become accessible in Germany under such an arrangement.

Stefan Neudoerfer, CSL Behring's chief negotiator in Germany, stated, "The performance-based payment model at national level which was agreed with the GKV-Spitzenverband is unique in Germany. It addresses key reimbursement challenges, such as the question of long-term efficacy, which is inherent for any one-time therapy. Reimbursement is linked to treatment success of the individual patient."

However, another high-profile outcome-based agreement in Germany signed in 2023 for BioMarin's Roctavian (valoctocogene roxaparvovec), a gene therapy for severe haemophilia A which was later terminated. The contract stipulates that reimbursement is linked to patient outcomes, with refunds required if real-world efficacy falls short however the agreement was dropped later.

In Spain, regional health authorities frequently apply risk-sharing agreements, particularly for hospital-dispensed and oncology medicines. A notable example comes from Galicia, which became the first Spanish region to introduce a risk-sharing procurement model for vaccines. Under this agreement, more than EUR 7.2 million was allocated for high-dose influenza vaccines, with reimbursement levels linked directly to health outcomes achieved in patients.

Looking ahead, Spain is also positioning itself at the forefront of innovative pricing reforms. The Health Technology Assessment Agency (AETS) of the Carlos III Health Institute (ISCIII) announced that beginning in January 2026, it will lead a three-year project to test dynamic pricing models across Europe.

According to Director Carlos Martín Saborido, the initiative will explore how price adjustments over time based on evolving real-world evidence and treatment outcomes could be used to improve both affordability and timely access to innovative medicines.

In France, alternative payment contracts remain uncommon, as drug pricing continues to be driven largely by population-level purchase volumes and clawback mechanisms designed to control total pharmaceutical spending.

However, France's Social Security Finance Act (LFSS) 2023 proposed a legal framework to support the funding of one-off treatments, particularly advanced therapy medicinal products (ATMPs).

The existing 2021–2024 framework agreement between the industry association Leem and the Economic Committee for Health Products (CEPS) already includes provisions for innovative reimbursement models. According to CEPS, ATMPs launched in France must undergo an economic evaluation due to their significant impact on patient care pathways and healthcare organization.

These evaluations serve two main purposes:

- Price negotiation: The initial reference price is set at the level where the medicine is dominant (more effective and no more costly than existing alternatives). A higher price may then be justified based on the therapy's ASMR (clinical added value)

- Risk identification: The analysis helps identify key uncertainties such as response rates and long-term outcomes, which guide the design of financial risk-sharing mechanisms

Under Article 54, France plans to implement a hybrid managed entry agreement (MEA) model combining outcome-based pricing with staggered payments. Hospitals will initially pay a flat price, reimbursed by sickness funds—or, if a negotiated price is lower, that amount will apply instead. The remaining balance will be paid to manufacturers in instalments linked to treatment outcomes.

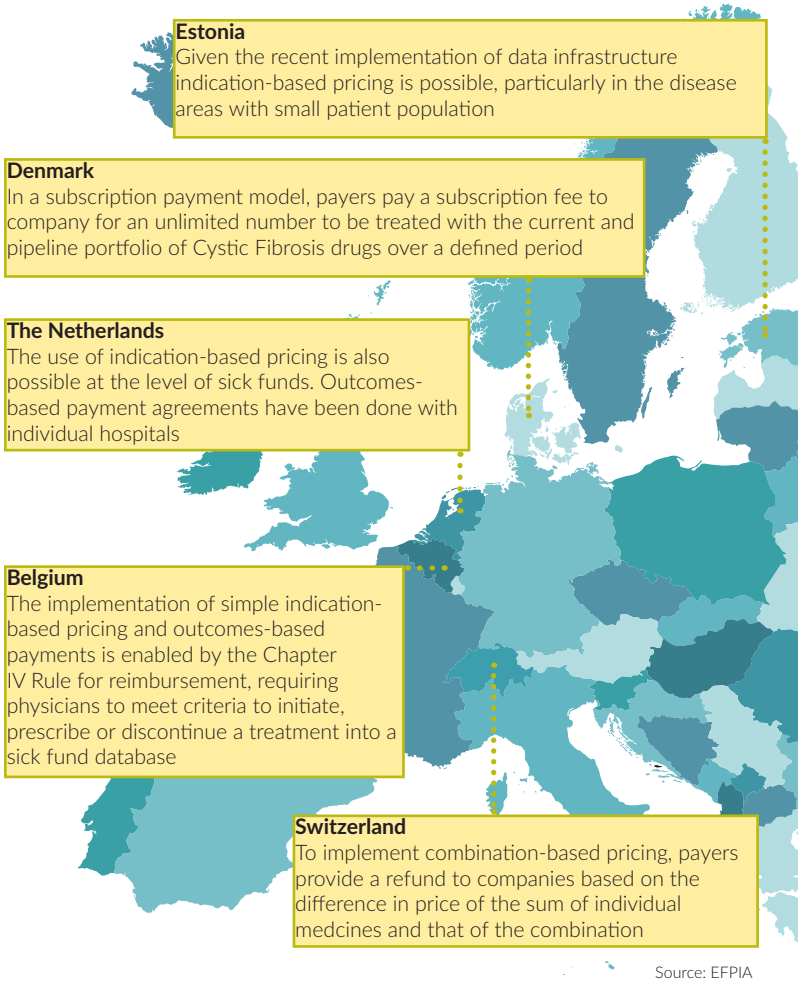
The specific outcome metrics, number and timing of payments, and data collection responsibilities will be determined through negotiation. Manufacturers will be accountable for generating real-world evidence, and in cases of treatment failure such as patient death or a switch to another therapy they may be required to refund part of the payments exceeding the cost of the comparator treatment.

Other Countries Are Also Experimenting

The Netherlands has introduced bundled payment models in chronic disease care, covering conditions such as type 2 diabetes, COPD, and vascular risk management, with the goal of shifting focus to primary care and avoiding more costly hospital treatments.

In Denmark, the Danish Medicines Council has recommended Hemgenix for adults with severe or moderately severe hemophilia B. The decision follows an outcomes-based agreement with the company, under which hospitals will only pay as long as the treatment remains effective.

Subscription-style "Netflix" models are also being tested internationally. For example, Australia negotiated a five-year, AUD 1 billion contract for unlimited access to hepatitis C antivirals, delinking spending from patient numbers.



Source: EFPIA

In Latin America, progress has been slower, but early pilots exist. Brazil launched its first risk-sharing agreement in 2019 for Spinraza in spinal muscular atrophy. Although this was a milestone, the absence of a formal regulatory framework has limited broader uptake. Bill 677, introduced in 2021, aims to formalise such contracts but has yet to pass into law. For now, Brazil's HTA agency CONITEC continues to evaluate new drugs for formulary inclusion, but performance-based reimbursement remains confined to exceptional cases.

Mexico is somewhat further along, as its federal procurement body, Mexico's Coordinating Commission for Negotiating the Price of Medicines and Other Health

Inputs (CCPNM) has integrated risk-sharing into its price negotiations. For selected innovative therapies, particularly in oncology and cardiovascular disease, Mexico has piloted performance-linked models that require manufacturers to refund payers if outcomes fall short. This represents a tentative but significant step toward value-based pricing.

What is the Place of Alternative Payment Models in the Future?

Alternative pricing and payment models can play a role in accelerating patient access while addressing key healthcare challenges linked to novel treatments, such as uncertainties around long-term outcomes, affordability, and budgetary pressures. Several companies and countries have already started adopting such mechanisms, which can serve as a lesson for others in the future; both good and bad.

With the EU Health Technology Assessment Regulation (HTAR) now in effect since January 12, 2025, and Joint Clinical Assessments (JCAs) being implemented across Member States, the EU is taking major steps toward a more streamlined and collaborative health technology assessment process. Similarly, establishing a dedicated framework for novel, orphan, and rare disease drugs could help facilitate early and equitable access to innovation through alternative pricing and payment models. Such a framework would encourage early dialogue between stakeholders, improve predictability, and foster flexibility on both sides.

While these models often come with additional costs related to data collection and monitoring, payers and industry should collaborate to develop practical data solutions that ensure transparency and access to information while minimizing administrative burden.

Overall, aligning alternative pricing and payment models with the joint framework could be a promising step particularly for smaller countries to enhance negotiation capacity and expand access to high-cost, innovative medicines.

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NAVLIN Insight: FDA Announces National Priority Voucher Recipients

Raechel Pusateri

NAVLIN BRIEF:

- The U.S. Food and Drug Administration (FDA) has unveiled the first recipients of its new Commissioner's National Priority Voucher (CNPV) pilot program. Designed to fast-track drug reviews for products that align with U.S. national interests, the program reduces FDA review timelines from nearly a year to as little as one month
- The inaugural cohort includes nine products ranging from treatments for Type I diabetes and pancreatic cancer to fertility treatments and domestically manufactured anesthetics and antibiotics
- The program's eligibility criteria reflect a broad set of strategic priorities, including addressing public health crises, advancing innovation, meeting large unmet medical needs, strengthening domestic manufacturing, and—most notably—improving affordability. The inclusion of pricing as a selection factor marks a significant shift in FDA policy, aligning with the Trump administration's push for Most Favored Nation (MFN) drug pricing

THE DETAILS

SILVER SPRING, MD, United States—This month, the Trump administration announced the first round of voucher recipients under the new Commissioner's National Priority Voucher (CNPV) pilot program.

The CNPV pilot is intended to speed up drug review timelines for drugmakers "supporting U.S. national interests."

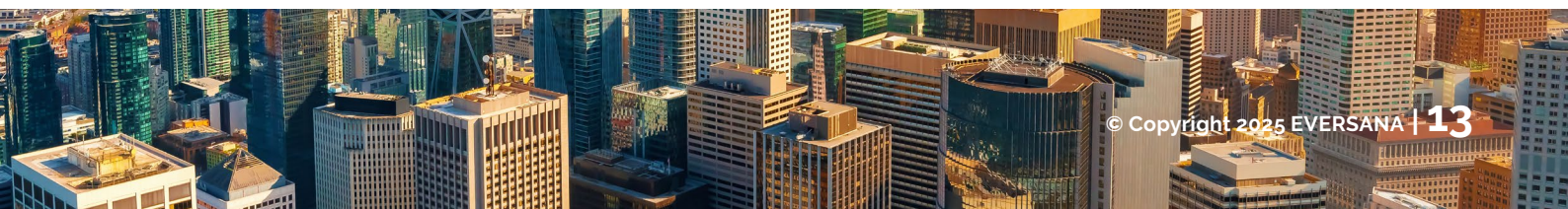
According to the agency, the new voucher may be redeemed by drug developers to participate in a novel priority program by the FDA that shortens its review time from approximately 10-12 months to 1-2 months following a sponsor's final drug application submission.

Products selected for review under the first round of the CNPV pilot include the following:

- EMD Serono's investigational fertility treatment, Pergoveris
- Sanofi's Tzield (teplizumab) for Type I diabetes
- Achieve Life Sciences' cytisinicline for nicotine vaping addiction
- Regeneron's DB-OTO for deafness
- Dompé Farmaceutici S.p.A.'s Oxervate (cenegermin-bkbj) for blindness
- Revolution Medicines' RMC-6236 for pancreatic cancer
- Disc Medicine's bitopertin for porphyria
- Ketamine for domestic manufacturing of a critical drug for general anesthesia
- Augmentin XR for domestic manufacturing of a common antibiotic

To be eligible for the program, applicants must demonstrate alignment with one or more of the program priorities, which include the following:

- Addressing a U.S. public health crisis, such as developing a universal flu vaccine that could provide broad protection against multiple strains of influenza, including those with pandemic potential
- Delivering more innovative cures for the American people. FDA notes that the focus for this priority is transformative impact that far outstrips the threshold for breakthrough therapy designation
- Addressing a large unmet medical need, such as a condition that available therapies do not adequately diagnose or treat, including drugs to treat or prevent rare diseases or addressing America's chronic disease crisis
- Onshoring drug development and manufacturing to advance the health interests of Americans and strengthen U.S. supply chain resiliency. Examples could include companies with new manufacturing establishments that shift manufacturing of essential medicines (such as generic sterile injectables) from foreign facilities to the U.S.; or a clinical trial that maintains robust U.S. enrollment to support generalizability for Americans against the U.S. standard of care



- Increasing affordability. This could include a company that lowers the U.S. price of a drug or drugs consistent with Most Favored Nation (MFN) pricing or reduces other downstream medical utilization to lower overall healthcare costs

"One of our core goals is to deliver more cures and meaningful treatments—especially ones that have an outsized impact on our most pressing national priorities," said FDA Commissioner Marty Makary, M.D., M.P.H. "We must modernize the review process and try new approaches to meet the needs of the American people."

Consideration of Affordability Signals New Era for FDA

The inclusion of price as a criterion for selection is one of the more interesting aspects of the new program and confirms that the Trump administration is using the FDA as an avenue to deliver on MFN drug pricing targets.

When discussing the program in July, Makary commented, "We can issue a national priority review voucher for companies that are promising to equalize the price between other OECD countries and the United States, with even other products that they currently have. We want to incentivize good behavior in the marketplace."

Although no additional details have been provided to clarify how the agency is considering affordability in the context of the new voucher program, the Trump administration's recent MFN agreement with EMD Serono included an announcement of the company's selection for the CNPV program.

According to the company, Pergoveris has the potential to be an innovative therapeutic option for women undergoing ovarian stimulation for Medically Assisted Reproductive (MAR) cycles. If approved in the U.S., Pergoveris would be the first and only combination of recombinant human follicle stimulating hormone (r-hFSH) and recombinant human luteinizing hormone (r-hLH).

The White House has characterized the candidate as a "lower-cost alternative to expensive medications already on the U.S. market," noting that if approved, "American patients stand to benefit even more from lower prices due to increased competition in the fertility drug space."

NAVLIN Insight: Preliminary Winners Announced for China's 11th Round of Centralized Procurement

Ray Yalisove

NAVLIN BRIEF:

- The preliminary results of China's 11th round of volume-based procurement (VBP) were announced, covering 55 drugs for a wide range of therapeutic areas, and representing a 75% fulfillment rate of all orders from 46,000 medical institutions
- The successful bidders' winning prices have not been officially disclosed, but the average price cut among both winning and non-winning bids is thought to be around 61%
- Officials sought to prevent involution (bid-rigging) while ensuring quality and honoring brand preferences, so smaller "barefoot companies" can no longer solely win based on steep price cuts but must consider long-term factors like brand-building, quality, and clinical reputation

THE DETAILS

BEIJING, China—This month, the preliminary results of China's 11th round of volume-based procurement (VBP) were announced. The round includes 55 drugs, expected to become available for patients by February 2026.

Drug varieties covered by the round encompass a wide range of therapeutic areas, including oncology, allergy indications, asthma, cardiovascular conditions, diabetes, infections, and neurological disorders.

Tough Competition

Early Monday morning at the procurement site in Qingpu District, Shanghai, a Daily Economic News reporter documented streams of company representatives queuing with their documents well ahead of the submission deadline. This year's competitive fury was deemed the most intense of all previous rounds.

A company representative told Cailian Press that their enterprise was only bidding to supply dihydroxypropyl theophylline injection and believed its chances would depend on the price. While fierce competition was observed between dozens of bidders, the maximum tally of companies able to make the shortlist is 10.

A spokesperson for an Indian generic drugmaker said Chinese companies were tough to battle. Local companies can control their raw material supply, packaging materials, and excipients. Meanwhile, foreign enterprises mainly import excipients and raw materials, with some even sourcing them from China despite the transportation costs. He asked, "How can we compete (with Chinese companies)?" Regardless, he still places bids because it's the only way to secure most of China's market.

The results released yesterday represent a 75% fulfillment rate of all orders from 46,000 medical institutions. A total of 445 companies placed bids for 794 products, with 453 bids from 272 enterprises shortlisted.

While the successful bidders' winning prices have not been officially disclosed, GBI estimated, based on corporate quotes, that the average price cut among both winning and non-winning bids, was around 61%. Once again, original manufacturer bids largely surpassed the acceptable price ceiling, leading to their elimination.

Proposed Winners

While its website is largely inaccessible abroad, the National Joint Procurement Office reportedly revealed the proposed winners, including several suppliers of dapagliflozin oral immediate-release formulations: Hetero Labs, Nanjing Fang Shenghe Pharmaceutical, Shandong Lukang Pharmaceutical, and Beijing Weilin Hengchang Pharmaceutical. Dapagliflozin is a new diabetes drug first added to the National Reimbursement Drug List (NRDL) in 2019.

Oral immediate-release dapagliflozin is China's top-selling small molecule drug, with sales surpassing RMB 8 billion. Last year, sales in public hospitals hit RMB 5.352 billion, marking the product as the only item in this year's batch to boast an annual sales amount above RMB 5 billion.

For pravastatin oral immediate-release formulations, it proposed Nanjing Daoqun Pharmaceutical, Shanghai Modern Pharmaceutical, and Hanhui Pharmaceutical; and for metformin empagliflozin tablets, it favored Changzhou Sunshine Pharmaceutical and Qilu Pharmaceutical.

Multiple A-share listed drugmakers reportedly announced their expected product selection, such as Jiudian Pharmaceutical which expects dapagliflozin tablets, nicorandil tablets, and loxoprofen sodium gel patches

to be selected, and Fu'an Pharmaceutical, along with its subsidiaries, expect up to eight products to be selected, with five products, like desloratadine oral solution and metformin empagliflozin tablets, failing to win.

Regarding loxoprofen patches/loxoprofen patches, Jiudian Pharmaceutical was not the only company to reportedly secure a preliminary win. So did Liqiang Pharmaceutical and Taide Pharmaceutical. Lead Chemical Co., Ltd., a subsidiary of Daiichi Sankyo, the original product manufacturer, lost the bid.

For the groundbreaking PARP inhibitor, olaparib oral immediate-release formulation, which secured more than one billion yuan in sales among public hospitals last year, Huadong Medicine (Xi'an) Bohua Pharmaceutical Co., Ltd., Tibet Jinyue Pharmaceutical Co., Ltd., Shanghai Xuantai Pharmaceutical Technology Co., Ltd., and Qilu Pharmaceutical (Hainan) Co., Ltd. won bids. Meanwhile, Hunan Kelun Pharmaceutical Co., Ltd. and CSPC Ouyi Pharmaceutical Co., Ltd. are able to place a follow-up bid and potentially obtain a preliminary win.

Optimized Rules for Balanced Competition

Officials sought to prevent involution (bid-rigging) while ensuring quality, which they reportedly achieved. This year, medical institutions were allowed to request specific brands of medicines, and 77% took advantage of this freedom, thus intensifying competition between bidders.

In support of this round's consideration of brand preferences, Mao Zongfu, director of the Global Health Research Center at Wuhan University, said, "The products and brands we're procuring this time have been used long-term by patients in different medical institutions. Some doctors and patients have developed certain perceptions of them, especially elderly patients. They know exactly how many pills to take and when to take them once they recognize a brand. Switching to another brand might involve different dosage forms and specifications. This change makes it easier for patients to continue using these products, especially those with chronic diseases and elderly patients, without altering their basic medication rules."

In this round, small-scale pediatric injections and oral solutions benefited from differential price calculations, incentivizing companies to participate. Guo Peng, director of the Department of Pharmacy at Beijing Children's Hospital, Capital Medical University, explained, "Since the pediatric patient population is smaller than that of adults, only when companies' reasonable profits are guaranteed can they be incentivized to invest in research and development and production."

While this year's competitive intensity trumped all previous rounds, the bidder success rate was relatively high. A variety of measures benefited bidders, including a 100 million yuan product scale minimum, anchor prices that prevented the influence of ultra-low bids, and a revival mechanism for initially unsuccessful bids. The revival mechanism gives bidders another chance if they are excluded from the initial shortlist by carrying out a second round of price reductions.

Describing the responsibility of bidders to justify low prices, Gu Hai, director of the Center for Public Health Management and Medical Security Policy Research at Nanjing University, said, "For the company that won the bid with the lowest price, they are required to provide a detailed explanation of the cost of their lowest quote to ensure that we believe the quality is reliable and that we can confidently supply it to clinical settings."

Notably, the average difference between prices of the winning products was much smaller compared to previous rounds.

In a 21st Century Business Herald report, Director Gu Hai said this year's price quotations are "normal and stable," and devoid of large-scale severely low prices, due to policy optimization.

In previous rounds, drugmakers with a tiny market share who succeeded through severe price reductions were known as "barefoot companies." Now, companies can no longer solely focus on cost control but must consider long-term factors like brand-building, quality, and clinical reputation.

Director Gu Hai explained, "For example, this year's centralized procurement rules set a price anchor point, using 50% of the average price of shortlisted drugs as the anchor point for calculating the price difference. If a company's bid is lower than this 'anchor point,' it will not interfere with other companies that are bidding normally, thus avoiding excessive competition among companies."

The Director added that bid-rigging was contained through restrictions on interrelated companies. Those with ties in equity, license transfers, or contract manufacturing were treated as a single entity as a preventative measure against collusion.

A "first-report leniency" mechanism to dismantle alliances of interest among bidders and a credit evaluation system are also being employed as additional cautionary measures. Furthermore, monopolization was countered by a ceiling limit where the volume of a winning bid may not exceed half of the product's total procurement volume.

Shifting Profit Structures for a Healthy Industry

While VBP has no direct relationship with corporate innovation, Chang Feng, Dean of the International Hospital Business School of China Pharmaceutical University, said it indirectly bolsters innovation through shifting generic drug profit structures: "Centralized procurement controls the profits of mature generic drugs within a reasonable range, which not only prevents companies from neglecting innovation due to excessive profit-seeking, but also provides companies with stable cash flow through volume guarantees, laying the foundation for innovative research and development. At the same time, the rule of reporting volume by brand is also conducive to promoting the increase of industry concentration, and hospitals tend to choose brands with mature clinical validation and stable usage habits."

The VBP program was launched in 2018 by China's National Healthcare Security Administration (NHSA) to alleviate the financial strain on patients and the national insurance fund. It focuses on drugs with expired patent protection that have an established, reliable reputation in clinics.

To date, 490 drugs have been successfully procured since the program's establishment. It is known to have struck down China's problem of pharmaceutical "kickback sales" and uses increasingly optimized measures to balance price discounts with quality standards and healthy competition.

MHRA & NICE Aim to Align Decisions, Cut MA-to-Guidance Time to 0–3 Months

Date: 9 Oct 2025 | Tags: #Policy & Regulation #HTA Decisions # Pricing & Reimbursement #Europe #MHRA #NICE

NAVLIN BRIEF:

- During a joint webinar, the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE) announced plans to align regulatory and HTA timelines, reducing the gap between marketing authorization and NICE guidance to as little as 0–3 months through an integrated scientific advice process
- Under the new aligned pathway, NICE appraisals and guidance publication can occur in parallel with MHRA reviews, allowing faster access to treatments while both agencies maintain independent evaluation standards
- The refreshed joint service, set for full launch in April 2026, will replace the current MHRA–NICE advice model, offering streamlined coordination, single payments, and greater clarity on evidence requirements

THE DETAILS

LONDON, United Kingdom—During a joint webinar, the MHRA and NICE outlined their shared ambition to synchronize regulatory and HTA decisions, aiming to reduce the time between marketing authorization (MA) and NICE guidance to as little as 0–3 months. The initiative aims to provide integrated scientific advice that supports informed and timely decisions for patients and the NHS.

As part of this collaboration, NICE and MHRA have strengthened operational information sharing and introduced deferral publications to give stakeholders greater clarity on when NICE will evaluate medicines that receive an MA. Both agencies will continue to operate independently while maintaining their distinct evaluation standards.

Key changes under the aligned pathway include:

- NICE decisions to run in parallel with MHRA reviews, closing the current 90-day gap
- Appraisal committee meetings, as well as draft and final draft guidance, may be held and published before marketing authorization
- Priority scheduling for medicines following the aligned pathway

To utilize the aligned pathway, companies must register their products in PharmaScan at least three years prior to MHRA market authorization and secure global-level approval, committing to adhere to the aligned process. Submissions to NICE must be made prior to MHRA authorization, allowing NICE guidance to be published simultaneously with the MA decision.

The refreshed joint service will replace the current MHRA–NICE scientific advice model, aiming to increase user confidence and clarity on evidence requirements through deeper technical collaboration. It is also expected to minimize unforeseen delays, enable aligned decisions, simplify payments through a single fee structure, and deliver a more coordinated user experience.

Development of the integrated service is planned from May to December 2025, followed by a proof-of-concept launch in early 2026 and a full launch in April 2026.

France's PLFSS 2026 Proposes Changes to Early & Direct Access

Date: 17 Oct 2025 | Tags: #Pricing & Reimbursement #Policy & Regulation #HTA Decisions #Europe #PLFSS #HAS

NAVLIN BRIEF:

- France's draft Social Security Financing Bill (PLFSS) for 2026 introduces changes to France's early and direct access systems for innovative medicines, two key mechanisms that currently allow patients faster access to promising treatments
- The draft makes early access discretionary and adds the criteria for such medicines to be "presumed innovative notably with regard to a clinically relevant comparator." The reform would also remove the therapeutic impasse requirement in the direct access route and limit reimbursement to a 12-month period following the opinion of the Haute Autorité de Santé (HAS). Beyond that, manufacturers would be required to provide treatments free of charge
- Commenting on the measures, Leem, the professional organization of pharmaceutical companies, stated the reform of early access "threatens the last lever of rapid access to therapeutic progress for French patients." By limiting eligibility and ending free access beyond twelve months, the organization said, France risks falling behind its European neighbours, noting that only 60% of medicines authorized at the European level since 2020 are currently available in France

THE DETAILS

PARIS, France—The draft Social Security Financing Bill (PLFSS) for 2026, presented by the French government, introduces changes to France's early and direct access systems for innovative medicines, two key mechanisms that currently allow patients faster access to promising treatments.

According to the bill, early access the exceptional pathway that allows use of some treatments for serious, rare or disabling diseases before the usual reimbursement negotiation is reformed as a discretionary, pre-marketing authorization route focused on medical innovation.

As a result, under article 34, the draft adds the criteria for such medicines to be presumed innovative notably with regard to a clinically relevant comparator.

Meanwhile, the reform removes the requirement that direct access be reserved for patients in a therapeutic impasse. Direct access is instead codified as a separate ministerial route that can be granted per indication for up to three years, enabling patients to benefit from medicines that already hold marketing authorization in one or more indications where those indications meet defined thresholds of medical benefit and improvement. Direct access explicitly excludes products already benefiting from early access.

Under the bill, Social Security funding is limited to a defined initial window: direct-access products and certain early-access products receive public coverage for twelve months from the publication event specified in the law. If an economic-evaluation opinion is published later, this twelve-month paid period can be extended by a further twelve months. After the paid period, the marketing-authorization holder is required to supply the product free of charge for the remainder of the authorized exceptional-access period and to meet a minimum twelve-month continuity obligation for patients who started treatment under the scheme, except where continuing treatment is precluded by safety reasons.

The draft also requires companies seeking direct access or early-access admissibility to commit to ensuring appropriate and continuous national supply, to guarantee continuity of treatments initiated during the exceptional-access period for at least twelve additional months after that period, and to provide the product free of charge for specified post-coverage periods. Companies may declare a maximum indemnity for early months' supply to hospitals in defined circumstances, must publish that amount, and must report annually on turnover and units supplied under the scheme.

Industry Reaction

The government argues that these adjustments are meant to improve regulatory predictability and control healthcare spending. However, the pharmaceutical industry has reacted with alarm, as Leem's president, Thierry Hulot underscores that the measures sacrifice therapeutic progress and access to treatments in favor of purely accounting logics.

"Behind every budget line, there are patients who are waiting for a drug, caregivers who want to have the right treatments, and companies that are committed to France. If we want to preserve our ability to provide care, we must put health back at the heart of public decisions," Hulot stated.

The group explains the reform of early access "threatens the last lever of rapid access to therapeutic progress for French patients." By limiting eligibility and ending free access beyond twelve months, the organization said, France risks falling behind its European neighbours, noting that only 60% of medicines authorized at the European level since 2020 are currently available in France.

Additionally, the group points out that under the guise of predictability, the PLFSS 2026 further increases the tax burden on pharmaceutical companies, widening a catastrophic competitiveness gap with our European neighbours, at a time when global investments are now heading towards the U.S.

Belgium Announces Mandatory Pharma Discounts in 2026 Health Budget

Date: 22 Oct 2025 | Tags: #Pricing & Reimbursement #Policy & Regulation #Europe #Clawback #NIDHI

NAVLIN BRIEF:

- Belgium has announced its health budget for 2026 which sets aside an additional EUR 1.566 billion investment, bringing the total healthcare budget to EUR 41.297 billion. Of the funding, EUR 228 million will be earmarked specifically for the pharmaceutical sector
- Additionally, the budget presents a range of reforms to ensure that public spending delivers effective, sustainable, and high-quality care. "Medicines are becoming more expensive worldwide and the world is in turn becoming unpredictable," emphasized the Federal Health Minister, Frank Vandenbroucke. "In difficult times, you have to do what you have to, to ensure that the healthcare system remains strong. Our healthcare system is strong thanks to the solidarity on which it is based. But we have to be careful with that solidarity"
- As such, the reform package includes a mandatory discount from pharmaceutical companies, which will contribute EUR 80 million through reduced prices on medicines. In addition, companies will invest EUR 10 million in the Post-Reimbursement Fund, which will stimulate research into better, more personalized treatments

THE DETAILS

BRUSSELS, Belgium—The Belgian government has announced a EUR 1.566 billion investment in the country's healthcare system as part of the 2026 health budget, aimed at ensuring access to affordable and high-quality care for all citizens.

The Federal Health Minister, Frank Vandenbroucke, emphasized: "Those who are sick must be helped. Without having to worry about unaffordable invoices."

"Medicines are becoming more expensive worldwide and the world is in turn becoming unpredictable," he added: "In difficult times, you have to do what you have to, to ensure that the healthcare system remains strong. Our healthcare system is strong thanks to the solidarity on which it is based. But we have to be careful with that solidarity."

As such, the investment of EUR 1.566 billion will increase the budget for 2026 to EUR 41.297 billion. However, Vandenbroucke explains, "this massive investment does not mean that we can let everything take its course." He adds that if the tap is left open and no measures are taken to use the solidarity resources in a targeted way, "there is a risk of a significant overrun of the budget."

In July, the government gave further direction to the 2026 target through the assignment letter. In summary, considering the previously decided efforts and the technical estimates from September, this means that interventions amounting to EUR 470.775 million are still required to avoid a budget slippage.

Overall, proposals were asked to be drawn up, with the budget being divided as follows:

The Pharmaceutical Sector & Directing Funding

"Within the Belgian healthcare system, we use too much medication," the Health Minister notes. "If we do nothing, the increase in pharmaceutical spending would take up 64% of the growth norm this year. It was decided in the coalition agreement that we will tackle the waste of

medicines, that we will prescribe and reimburse in a more targeted and precise way. More care for our money. That is why the Pharmaceutical Multi-Year Framework was drawn up earlier this year."

As a result, EUR 228 million has been allocated for this sector, on top of previously decided efforts. However, if this target is exceeded, the Minister emphasizes that the pharmaceutical industry will have to cover the deficit itself through an additional levy on turnover.

This means a mandatory discount from pharmaceutical companies will be in place, which the Minister hopes will generate EUR 80 million through reduced prices on medicines. The budget explains, each company will pay a share of this total amount proportional to its corrected total turnover for reimbursable products from the year 2026 and for each subsequent year (T-year)medicines, that we will prescribe and reimburse in a more targeted and precise way. More care for our money. That is why the Pharmaceutical Multi-Year Framework was drawn up earlier this year."

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Corrected Turnover:

- The company's adjusted total turnover for reimbursable pharmaceutical specialties = The company's total turnover for its reimbursable pharmaceutical specialties for the year T-1, as declared by the company in the context of its VAT return (art. 191.15) minus the company's total turnover for its reimbursable pharmaceutical specialties for the year T-1, as declared by the company in the context of its VAT return (art. 191.15), which belong to small markets (active ingredient turnover < EUR 3 million, reimbursed in categories A or B)

- The total turnover of the company for its reimbursable pharmaceutical specialties for the year T-1, as indicated by the company in the context of the turnover tax return (Article 191.15), for which the effect lasts longer than 10 years (i.e., also for generics) and which are reimbursed in category A or B, the application of Article 35ter of the Act (the reference price system) applies

- 50% of the turnover of products for the year T-1, temporarily included in the list of reimbursable specialties with code T, as indicated by the company in the context of the turnover tax return (Art. 191.15)

Additionally, companies will invest EUR 10 million in the Post-Reimbursement Fund, which will stimulate research into more effective, personalized treatments.

"Everyone knows someone who underwent chemo and saw the impact that certain treatments can have. With the Post Reimbursement Fund, we want the scientific world and doctors in the field to conduct more thorough research into overtreatment, with an eye for the well-being of patients," explains Vandenbroucke. "The research should ultimately lead to better and appropriate treatments."

Other Measures for the Sector Include:

The Belgian National Action Plan against Antimicrobial Resistance contains several measures to make the use of antibiotics more rational. One of these is the delivery of antibiotics per treatment period, so that patients receive exactly the dose they need. This helps to avoid overconsumption and self-medication, two major causes of resistance. "Because the more often antibiotics are used unnecessarily, the better microbes adapt and become insensitive to treatment," the Ministry explains. "This threatens to make infections more difficult to fight." (EUR 3.3 million will be invested for this measure).

Deepening of partial billing in hospitals from 85% to 78%. For example, the system will be strengthened whereby hospitals can make competitive price agreements with pharmaceutical companies through their tenders. The measure confirms their role as an active negotiating partner and helps to make the financing of medicines more sustainable.

The budget also plans counteracting the tendency to always prescribe the most expensive available therapy, while cheaper medicines are available, with a new measure that will be worked out in the course of 2026. (Allocation of EUR 42 million).

It was previously announced that a new procedure has been developed to be able to reimburse promising and new therapies more quickly to patients who need them ('Early and Equitable Fast Access procedure'). This new measure is financed by the introduction of a minimum contribution per package: from now on patients pay at least EUR 2 per box, or EUR 1 for people with a preferential allowance.

The Ministry underscores this does not mean that all medicines will become more expensive, but it does mean that the co-payment for medicines - for which patients pay less than EUR 1 or EUR 2 per package - will be

raised to that minimum. The budget will therefore invest the proceeds of this measure directly in the Early and Equitable Fast Access procedure.

To protect people with high sickness expenses even better, the Ministry underscores it is extending the maximum bill in healthcare to medicines in reimbursement categories Cs and Cx, which include, for example, anti-allergy drugs (the number of allergies is on the rise). Investment of EUR 8.9 million. This investment can also be made thanks to the introduction of a minimum co-payment (Total allocation EUR 26.2 million)

Meanwhile, Belgium has been one of the countries with the highest use of antacids in Europe for years: at least 1 in 5 Belgians takes them. Only Spain, Italy and the Netherlands precede Belgium. Between 2004 and 2017, its use tripled, and it has continued to rise year after year ever since. What is even more worrying: many people take antacids (much) longer than recommended.

Therefore, the antacids in reimbursement category B will be moved to category Cx. The antacids in reimbursement category A will remain unaffected, as they are used for people with serious conditions (such as Barrett's syndrome). The increase in the co-payment will be accompanied by an information campaign from the government about the proper use of antacids. (Allocation of EUR 53.9 million)

The reimbursement of cholesterol-lowering drugs, such as statins, ezetimibe and combinations thereof, will also be treated in reimbursement category C from now on.

"Today, cholesterol-lowering drugs are prescribed very broadly, including to people with a rather low risk of cardiovascular disease," the Ministry notes. "However, they can often lower their cholesterol just as effectively through lifestyle modifications." In addition, more than half (55%) of patients who take cholesterol-lowering drugs for primary prevention stop their treatment over time leaving medicines unused in the cupboard and the treatment loses its usefulness.

The General Council also wants cholesterol-lowering drugs to be used in those patients who benefit most from them, taking into account all factors such as risk of cardiovascular disease, age and frailty of the patient. Therefore, this measure will be accompanied by an information campaign by the government on the correct use of cholesterol-lowering drugs, including their importance for the prevention of cardiovascular diseases. (Allocation of EUR 29.4 million).

EU HTAR Webinar Confirms Four JSC Request Slots Scheduled for 2026

Date: 27 Oct 2025 | Tags: #Pricing & Reimbursement #HTA Decisions #Cross-border Initiatives #JSC

NAVLIN BRIEF:

- During the recent EU HTA Regulation: Webinar for Health Technology Developers, it was reported that 10 Joint Scientific Consultations (JSCs) were planned for this year, with seven medicinal products already selected across the two submission slots
- Speakers reported that among the nine ongoing joint clinical assessments (JCAs), dossiers for tovorafenib and an ATMP for melanoma are currently undergoing completeness checks, while six JCAs have finalized their scopes and one is still under development
- During the webinar, the importance of realistic timelines in letters of intent was emphasized, especially for planned EMA submissions and indication claims, to ensure effective capacity planning. Numerous letters of intent have been delayed beyond their original submission dates, posing coordination challenges

THE DETAILS

BRUSSELS, Belgium—During the webinar titled "*The EU HTA Regulation: Webinar for Health Technology Developers of Medicinal Products*," hosted by SANTE HTA on October 17, 2025, Chairs and Co-Chairs of the Member State Coordination Group on Health Technology Assessment (HTACG) and its subgroups outlined the processes for JCA and JSC.

Sonia Pulido Sánchez, Co-Chair of the JSC Subgroup, shared updates on JSC activities, noting that 10 JSCs were planned for 2025, with efforts underway to expand capacity in future years. Two submission slots were designated for health technology developers (HTDs):

- February 3–March 3, 2025, for medicinal products, and
- June 2–June 30, 2025, for both medicinal products and medical devices

A total of seven JSCs for medicinal products were selected for 2025, with three in the first slot and four in the second.

The first JSC outcome document was finalized by the JSC Subgroup and HTACG at the end of September.

Sánchez shared several positive initial observations:

- HTDs were highly responsive, resulting in efficient feedback loops.
- Briefing packages were clear and well structured, demonstrating that the current template is effective.
- Patients and clinical experts were identified and selected for four JSC procedures.
- Processes have run smoothly, with the first completed JSC providing valuable lessons and supporting the start of optimization efforts.

Looking ahead, Sánchez noted that the Implementing Regulation will require four JSC request periods to be offered next year. The Coordination Group will adopt its annual work program by November 30, outlining the number of JSCs to be initiated in 2026 and the corresponding request periods. She also reminded participants that, under Article 6.4 of the HTA Regulation, the Coordination Group will adopt its annual report by February 28 each year.

Anne Willemsen, JCA Co-Chair, provided an update on ongoing JCAs, reporting that nine assessments are currently in progress. Of these, dossiers for two products—tovorafenib, an orphan drug for pediatric low-grade glioma (LGG), and an advanced therapy medicinal product (ATMP) using autologous melanoma-derived tumor-infiltrating lymphocytes for melanoma have been submitted and are undergoing completeness checks. Six JCAs have completed the assessment scope stage, while one is still developing its scope.

Willemsen noted that only one JCA did not include an assessment scope explanation meeting. She emphasized the importance of realistic timelines in letters of intent, particularly regarding planned EMA submissions and indication claims, to support effective capacity planning. Many letters of intent have been postponed beyond their initial submission dates, creating coordination challenges.

She also emphasized the importance of the timely submission of the clinical overview and draft SmPC, noting that the number of PICOs is high, as expected.

For dossier confirmation checks, she reminded participants that the entire template must be completed, relevant guidance must be carefully followed, and evidence should be provided through systematic literature searches when no data are available for a specific PICO. If a dossier is found incomplete twice, the corresponding JCA will be discontinued.

Sara Couto, Co-Chair of the Methodologies and Procedures (MPG) Subgroup, said that the group is compiling insights from the first JCAs and documenting them for assessors and co-assessors.

So far, no major updates to methodological guidance have been deemed necessary, though some documents may require further clarification.

In the second part of the webinar, the European Commission conducted a training session on how to access and utilize the HTA IT Platform for JSC and JCA workflows, including the submission of early information, such as letters of intent, for HTA purposes.

UK Extends VPAG Exit Deadline Again

Date: 28 Oct 2025 | Tags: #Policy & Regulation #Europe #VPAG #DHSC #ABPI #Innovation

NAVLIN BRIEF:

- The UK pharma industry and government have, once again, extended the deadline for companies to leave the 2024 Voluntary Scheme for Branded Medicines Pricing (VPAG) to November 14, 2025
- Companies that decide to leave must transfer to the statutory pricing scheme and cannot reverse their decision. Companies that do not submit notice must remain in the scheme throughout 2026
- Recent withdrawals and suspended projects echo mounting concerns about stagnation in the UK, with the VPAG rates being a large part of the issue. Industry leaders and government officials agree that urgent action is needed to restore confidence and secure the UK's future as an innovation hub. Global policy shifts are compounding the issues the UK faces, as tariff threats and the Trump administration's Most Favored Nation (MFN) loom, drawing investment from the UK to the U.S.

THE DETAILS

LONDON, United Kingdom—The Association of the British Pharmaceutical Industry (ABPI) and the UK government have, once again, agreed to extend the deadline for companies to give notice if they intend to leave the 2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG).

Under the revised timeline, companies now have until November 14, 2025, to submit their notice to exit the scheme, two weeks later than the first extension, which pushed the deadline to October 31. The extension supersedes the previous extension agreed in September.

The deadline was initially the end of September. The ABPI stressed that while a similar extension was granted in 2024, this year's adjustment is unrelated to that process and will not affect deadlines in future years of VPAG.

Companies that notify their departure before the new November deadline will not be able to reverse their decision. Those that do not submit notice must remain in the scheme throughout 2026.

Any companies exiting VPAG will instead move onto the statutory scheme for branded medicines.

The adjustments have been introduced to give companies additional time to weigh their options amid what ABPI described as "ongoing global uncertainty."

Once hailed as a global life sciences leader, the UK is now facing a wave of disinvestment; AstraZeneca (AZ), a British pharma giant, announced plans to pause a planned £200 million investment in the UK, shortly after MSD announced it will also halt research operations in London.

Earlier this year, AZ also withdrew its £450 million expansion plan in Speke after failure to secure government support. GSK, another British company, revealed that it will invest $30 billion in research and development and supply chain infrastructure in the U.S. over the next five years.

The recent withdrawals and suspended projects echo mounting concerns about stagnation, coinciding with an ABPI report showing the UK losing ground in R&D, clinical trials, and foreign direct investment; Industry leaders and government officials agree that urgent action is needed to restore confidence and secure the UK's future as an innovation hub.

Global policy shifts are compounding the issues the UK faces, as tariff threats and the Trump administration's Most Favored Nation (MFN) loom, drawing investment from the UK to the U.S.

What's Happening With the VPAG?

In August, the pharmaceutical industry and the UK government failed to reach an agreement on changes to the 2024 VPAG.

At the time, Wes Streeting gave the ABPI a "private ultimatum" to either accept the government's offer or conclude without an agreement, the latter of which has now been confirmed.

The review was tasked with finding a mutually agreed-upon way to address soaring VPAG payment rates. These rates now require pharmaceutical companies to make record payments of up to a quarter to a third (23.5%-35.6%) of their revenue from sales of branded medicines to the NHS.

Despite apparent "good faith and best efforts on both sides," industry and government have not been able to reach an agreed way forward that will meaningfully deliver on:

- The UK government's ambition for the life science sector and wider economic growth
- Industry's ambition to ensure the latest medical breakthroughs and treatments can reach all the NHS patients who can benefit from them
- The commitments set out in the UK-US Economic Prosperity Deal

The ABPI writes: "Specifically, industry and government have not been able to reach agreement on the changes needed to rapidly return the UK to single-digit, internationally competitive payment rates on medicines sales to the NHS, nor address the way in which NICE fundamentally values innovation, for which the standard decision-making parameters have not changed for almost a quarter of a century."

Overall, Richard Torbett, Chief Executive of the ABPI, called for a solution "that improves patient access to future innovation, allows the sector to fulfill its growth potential, and does not require industry to pay back nearly three times as much of its revenues as is required in other European countries."

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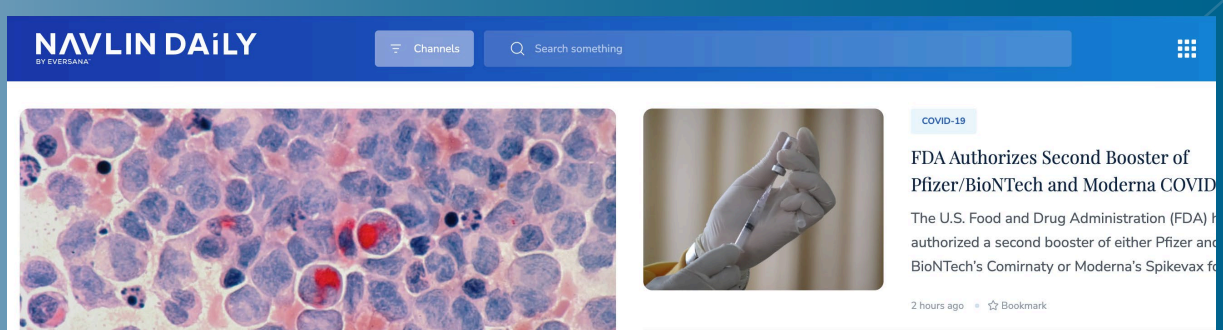

HTAs, Approvals, Launches & Price Changes

HTAs: France

- VYJUVEK; BEREMAGENE GEPERPAVEC; KRYSTAL BIOTECH; EPIDERMOLYSIS BULLOSA (INFANT); Infants with wounds presenting one or more mutations in the type VII collagen alpha 1 chain gene (COL7A1), from birth.; SMR (IMPORTANT); SMR (IMPORTANT); RECOMMENDED
- VYJUVEK; BEREMAGENE GEPERPAVEC; KRYSTAL BIOTECH; EPIDERMOLYSIS BULLOSA (PEDIATRIC); Paediatrics with wounds presenting one or more mutations in the type VII collagen alpha 1 chain gene (COL7A1).; SMR (IMPORTANT); SMR (IMPORTANT); RECOMMENDED
- VYJUVEK; BEREMAGENE GEPERPAVEC; KRYSTAL BIOTECH; EPIDERMOLYSIS BULLOSA (ADULTS); Adults with wounds presenting one or more mutations in the type VII collagen alpha 1 chain gene (COL7A1).; SMR (IMPORTANT); SMR (IMPORTANT); RECOMMENDED
- FABHALTA; IPTACOPAN; NOVARTIS; COMPLEMENT 3 GLOMERULOPATHY; Adult patients with a urinary protein/creatinine ratio (UPCR) ≥1g/g or recurrence after transplantation, after optimized standard treatment (except in cases of contraindication or intolerance).; SMR (INSUFFICIENT); NOT RECOMMENDED
- SPEVIGO; SPESOLIMAB; BOEHRINGER INGELHEIM; PUSTULAR PSORIASIS; Adult patients who require prevention of flares of generalized pustular psoriasis (GPP).; SMR (IMPORTANT); ASMR V (ABSENCE); RECOMMENDED
- SPEVIGO; SPESOLIMAB; BOEHRINGER INGELHEIM; PUSTULAR PSORIASIS; Adolescent patients aged 12 years and older who require prevention of flares of generalized pustular psoriasis (GPP).; SMR (IMPORTANT); ASMR V (ABSENCE); RECOMMENDED
- REKAMBYS; RILPIVIRINE; VIIV HEALTHCARE; HIV; Adolescents patients aged 12 years and older, weighing at least 35 kg who are virologically suppressed (viral load < 50 copies/mL) on a stable antiretroviral regimen for at least 6 months, with CD4 count > 200 cells/mm^3, no current or past evidence of resistance, and no history of virologic failure to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or integrase inhibitors (INIs).; SMR (IMPORTANT); ASMR V (ABSENCE); RECOMMENDED
- REKAMBYS; RILPIVIRINE; VIIV HEALTHCARE; HIV; Adolescents patients who are in other situations.; SMR (INSUFFICIENT); NOT RECOMMENDED
- VOCABRIA; CABOTEGRAVIR; VIIV HEALTHCARE; HIV; Adolescents patients aged 12 years and older, weighing at least 35 kg who are virologically suppressed (viral load < 50 copies/mL) on a stable antiretroviral regimen for at least 6 months, with CD4 count > 200 cells/mm^3, no current or past evidence of resistance, and no history of virologic failure to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or integrase inhibitors (INIs).; SMR (IMPORTANT); ASMR V (ABSENCE); RECOMMENDED
- VOCABRIA; CABOTEGRAVIR; VIIV HEALTHCARE; HIV; Adolescents patients who are in other situations.; SMR (INSUFFICIENT); NOT RECOMMENDED
- FEIBA; FACTOR VIII INHIBITOR BYPASSING ACTIVITY; TAKEDA; HEMORRHAGE; Adult patients who are in surgical situations with congenital factor VIII deficiency (hemophilia A) who are high responders and have developed an inhibitor against factor VIII.; SMR (IMPORTANT); ASMR V (ABSENCE); RECOMMENDED
- FEIBA; FACTOR VIII INHIBITOR BYPASSING ACTIVITY; TAKEDA; HEMORRHAGE; Adult patients who are in surgical situations with congenital factor IX deficiency (hemophilia B) who are high responders and have developed an inhibitor against factor IX, in cases where treatment with factor VIIa has failed.; ASMR V

(ABSENCE); RECOMMENDED

XURTA; LISDEXAMFETAMINE; HAC PHARMA; ADHD (PEDIATRIC); Children aged 6 years and older when the response to a previous treatment with methylphenidate is deemed clinically insufficient.; SMR (MODERATE); ASMR V (ABSENCE); RECOMMENDED

XURTA; LISDEXAMFETAMINE; HAC PHARMA; ADHD; Adult patients who are presenting with ADHD symptoms that were already present during childhood.; SMR (MODERATE); ASMR V (ABSENCE); RECOMMENDED

IMFINZI; DURVALUMAB; ASTRAZENECA; NSCLC (PLATINUM-CONTAINING CHEMOTHERAPY) (NEOADJUVANT TREATMENT); Adult patients with resectable cancer at high risk of recurrence, without EGFR mutations or ALK rearrangements, whose tumors express PD-L1 at a threshold < 1%.; SMR (INSUFFICIENT); NOT RECOMMENDED

IMFINZI; DURVALUMAB; ASTRAZENECA; NSCLC (ADJUVANT TREATMENT); Adult patients with resectable cancer at high risk of recurrence, without EGFR mutations or ALK rearrangements, whose tumors express PD-L1 at a threshold < 1%.; SMR (INSUFFICIENT); NOT RECOMMENDED

HTAs: Italy

AIMOVIG; ERENUMAB; NOVARTIS; PROPHYLAXIS OF MIGRAINE; Adult patients who have experienced at least 8 disabling migraine days per month in the last 3 months [defined as a MIDAS score ≥11], and who have already been treated with other migraine prophylaxis therapies with insufficient response after at least 6 weeks of treatment or who are intolerant to or have clear contraindications to at least three previous classes of medications for migraine prophylaxis.; RECOMMENDED

APIXABAN; APIXABAN; SANDOZ; STROKE PREVENTION IN ATRIAL FIBRILLATION; Adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, being 75 years or older, diabetes mellitus, or a prior stroke or transient ischemic attack (TIA).; RECOMMENDED

APIXABAN; APIXABAN; SANDOZ; TREATMENT OF DEEP VEIN THROMBOEMBOLIC EVENTS; Adult patients; RECOMMENDED

CASGEVY; EXAGAMGLOGENE AUTOTEMCEL; VERTEX; TRANSFUSION-DEPENDENT B-THALASSAEMIA; Adolescents aged 12 years and older for whom hematopoietic stem cell (HSC) transplantation is appropriate and a human leukocyte antigen (HLA)-matched related HSC donor is not available.; RECOMMENDED

CASGEVY; EXAGAMGLOGENE AUTOTEMCEL; VERTEX; TRANSFUSION-DEPENDENT B-THALASSAEMIA; Adults for whom hematopoietic stem cell (HSC) transplantation is appropriate and a human leukocyte antigen (HLA)-matched related HSC donor is not available.; RECOMMENDED

CASGEVY; EXAGAMGLOGENE AUTOTEMCEL; VERTEX; SICKLE CELL DISEASE; Adolescents aged 12 years and older with recurrent vaso-occlusive crises (VOCs), for whom hematopoietic stem cell (HSC) transplantation is appropriate and a human leukocyte antigen (HLA)-matched related HSC donor is not available.; RECOMMENDED

CASGEVY; EXAGAMGLOGENE AUTOTEMCEL; VERTEX; SICKLE CELL DISEASE; Adults with recurrent vaso-occlusive crises (VOCs), for whom hematopoietic stem cell (HSC) transplantation is appropriate and a human leukocyte antigen (HLA)-matched related HSC donor is not available.; RECOMMENDED

BONVIVA; IBANDRONIC ACID; ATNAHS PHARMA; POSTMENOPAUSAL OSTEOPOROSIS; Adult women who are postmenopausal and at high risk of fracture.; RECOMMENDED

AWIQLI; INSULIN ICODEC; NOVO NORDISK; DIABETES MELLITUS; Adult patients.; RECOMMENDED

BIMZELX; BIMEKIZUMAB; UCB; AXIAL SPONDYLOARTHRITIS (NON-RADIOGRAPHIC); Adult patients with objective signs of inflammation, detected by elevated C-reactive protein (C-reactive 3 protein) (CRP) levels and/or magnetic resonance imaging (MRI), who have responded inadequately to or are intolerant to

nonsteroidal anti-inflammatory drugs (NSAIDs).; RECOMMENDED

- BIMZELX; BIMEKIZUMAB; UCB; AXIAL SPONDYLOARTHRITIS; Adult patients who have responded inadequately to or are intolerant to conventional therapy.; RECOMMENDED
- BIMZELX; BIMEKIZUMAB; UCB; HIDRADENITIS SUPPURATIVA; Adult patients with an inadequate response to conventional systemic therapy for HS.; RECOMMENDED
- BIMZELX; BIMEKIZUMAB; UCB; PSORIASIS; Adult patients with moderate to severe disease, defined by PASI >10 or BSA >10% or BSA <10% or PASI <10 associated with lesions on the face, palms/plantars, nails, or genitals) who have shown lack of response or intolerance to conventional synthetic disease-modifying antirheumatic drugs (DMARDs).; RECOMMENDED
- BIMZELX; BIMEKIZUMAB; UCB; PSORIATIC ARTHRITIS; Adult patients who have had an inadequate response to, or who have been intolerant to, one or more disease-modifying antirheumatic drugs (DMARDs).; RECOMMENDED
- ANZUPGO; DELGOCITINIB; LEO PHARMA; ECZEMA; Adult patients for whom topical corticosteroids are inadequate or inappropriate.; RECOMMENDED
- ADEMPAS; RIOCIGUAT; BAYER; CTEPH; Adult patients with WHO functional class II to III disease that is inoperable or persistent or recurrent after surgical treatment, to improve exercise capacity.; RECOMMENDED
- ADEMPAS; RIOCIGUAT; EG PHARMA; HYPERTENSION; Adult patients.; RECOMMENDED
- ADEMPAS; RIOCIGUAT; EG PHARMA; HEART FAILURE; Adult patients with reduced ventricular systolic function.; RECOMMENDED
- CAMZYOS; MAVACAMTEN; BRISTOL MYERS SQUIBB; HYPERTROPHIC CARDIOMYOPATHY; Adult patients for whom standard therapy with non-vasodilating β_1 cardioselective β-blockers (atenolol, bisoprolol, acebutolol, metoprolol) or non-dihydropyridine calcium channel blockers (verapamil, diltiazem) is insufficient.; RECOMMENDED

HTAs: United Kingdom

- IMFINZI; DURVALUMAB; ASTRAZENECA; LIMITED-STAGE SMALL CELL LUNG CANCER; Adult patients who have not progressed after platinum-based chemoradiotherapy.; RECOMMENDED
- BETMIGA; MIRABEGRON; ASTELLAS; NEUROGENIC DETRUSOR OVERACTIVITY (PEDIATRIC); Pediatrics aged 3 to 17 years.; RECOMMENDED
- ANDEMBRY; GARADACIMAB; CSL BEHRING; HEREDITARY ANGIOEDEMA (PROPHYLAXIS); Adolescents aged 12 years and older.; CONDITIONALLY RECOMMENDED
- ANDEMBRY; GARADACIMAB; CSL BEHRING; HEREDITARY ANGIOEDEMA (PROPHYLAXIS); Adult patients.; CONDITIONALLY RECOMMENDED
- LORVIQUA; LORLATINIB; PFIZER; NSCLC (ALK+) (PREVIOUSLY UNTREATED WITH ALK INHIBITOR); Adult patients who have not had an ALK inhibitor.; RECOMMENDED

HTAs: Germany

- JAYPIRCA; PIRTOBRUTINIB; ELI LILLY; CLL (RELAPSED/REFRACTORY); Adults who have previously been treated with a Bruton tyrosine kinase inhibitor (BTKi) and not with a B-cell lymphoma 2 (BCL-2) inhibitor.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- JAYPIRCA; PIRTOBRUTINIB; ELI LILLY; CLL (RELAPSED/REFRACTORY); Adult patients who have previously

been treated with a Bruton tyrosine kinase inhibitor (BTKi) and a B-cell lymphoma 2 (BCL2) inhibitor and for whom idelalisib in combination with rituximab or bendamustine in combination with rituximab represents the appropriate individualized therapy.; MINOR ADDITIONAL BENEFIT; RECOMMENDED

- JAYPIRCA; PIRTOBRUTINIB; ELI LILLY; CLL (RELAPSED/REFRACTORY); Adults who have previously been treated with a Bruton's tyrosine kinase inhibitor (BTKi) and a B-cell lymphoma 2 (BCL-2) inhibitor and for whom venetoclax + rituximab is the appropriate individualised therapy.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- BREYANZI; LISOCABTAGENE MARALEUCEL; BRISTOL MYERS SQUIBB; FOLLICULAR LYMPHOMA GRADE 3B (RELAPSED/REFRACTORY); Adult patients after two or more lines of systemic therapy.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- KEYTRUDA; PEMBROLIZUMAB; MSD; MALIGNANT PLEURAL MESOTHELIOMA (PEMETREXED & PLATINUM CHEMOTHERAPY); Adult patients with unresectable, non-epithelioid malignant pleural mesothelioma.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- AUGTYRO; REPOTRECTINIB; BRISTOL MYERS SQUIBB; SOLID TUMORS (NTRK GENE FUSION); Adults with advanced tumors that harbor a neurotrophic tyrosine receptor kinase (NTRK) gene fusion and who have not previously received an NTRK inhibitor and where non-NTRK treatment options offer limited clinical benefit or have been exhausted.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- AUGTYRO; REPOTRECTINIB; BRISTOL MYERS SQUIBB; SOLID TUMORS (NTRK GENE FUSION); Adolescents aged 12 years and older with advanced tumors that harbor a neurotrophic tyrosine receptor kinase (NTRK) gene fusion and who have not previously received an NTRK inhibitor and where non-NTRK treatment options offer limited clinical benefit or have been exhausted.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- WAINZUA; EPLONTERSEN; ASTRAZENECA; HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (POLYNEUROPATHY); Adults with stage 1 or 2 polyneuropathy.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- ENHERTU; TRASTUZUMAB DERUXTECAN; DAIICHI SANKYO; BREAST CANCER HER2-ULTRALOW (IHC 0); Adults with unresectable or metastatic HR-positive, HER2-low or HER2-ultralow cancer who have received at least one endocrine therapy in the metastatic situation and who are not eligible for endocrine therapy as the next line of therapy.; MINOR ADDITIONAL BENEFIT; RECOMMENDED
- HETRONIFLY; SERPLULIMAB; ACCORD; SMALL CELL LUNG CANCER (COMBINATION); Adult patients with advanced cancer (ES-SCLC).; NON-QUANTIFIABLE ADDITIONAL BENEFIT; RECOMMENDED
- EMCITATE; TIRATRICOL; RARE THYROID THERAPEUTICS; PERIPHERAL THYROTOXICOSIS (MONOCARBOXYLATE TRANSPORTER 8 (MCT8) DEFICIENCY) (INFANT); Infants with monocarboxylate transporter 8 (MCT8) deficiency (Allan-Herndon-Dudley syndrome).; NON-QUANTIFIABLE ADDITIONAL BENEFIT; RECOMMENDED
- ALHEMO; CONCIZUMAB; NOVO NORDISK; HAEMOPHILIA (INHIBITORS OF BLOOD CLOTTING FACTOR VIII OR FACTOR IX); Adults with hemophilia A (congenital factor VIII deficiency) and factor VIII inhibitors with an indication for routine prophylaxis.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- ALHEMO; CONCIZUMAB; NOVO NORDISK; HAEMOPHILIA (INHIBITORS OF BLOOD CLOTTING FACTOR VIII OR FACTOR IX); Adults with hemophilia B (congenital factor IX deficiency) and factor IX inhibitors with an indication for routine prophylaxis, for whom on-demand treatment with bypassing preparations (human plasma fraction enriched with factor VIII inhibitor bypassing activity or eptacog alfa) alone represents the appropriate therapy for each patient.; CONSIDERABLE ADDITIONAL BENEFIT; RECOMMENDED
- KAFTRIO; ELEXACAFTOR & IVACAFTOR & TEZACAFTOR; VERTEX; CYSTIC FIBROSIS; Adults with cystic fibrosis who have at least one non-class I mutation in the CFTR gene that is not an F508del mutation or a gating mutation.; MAJOR ADDITIONAL BENEFIT; RECOMMENDED
- KAFTRIO; ELEXACAFTOR & IVACAFTOR & TEZACAFTOR; VERTEX; CYSTIC FIBROSIS (PEDIATRIC); Children aged ≥ 6 years who have at least one non-class I mutation in the CFTR gene that is not an F508del

mutation and not a gating mutation.; CONSIDERABLE ADDITIONAL BENEFIT; RECOMMENDED

- KAFTRIO; ELEXACAFTOR & IVACAFTOR & TEZACAFTOR; VERTEX; CYSTIC FIBROSIS; Adolescents aged less than 18 years who have at least one non-class I mutation in the CFTR gene that is not an F508del mutation and not a gating mutation.; CONSIDERABLE ADDITIONAL BENEFIT; RECOMMENDED
- KAFTRIO; ELEXACAFTOR & IVACAFTOR & TEZACAFTOR; VERTEX; CYSTIC FIBROSIS (PEDIATRIC); Children aged ≥ 2 to < 6 years who have at least one non-class I mutation in the CFTR gene that is not an F508del mutation and not a gating mutation.; NON-QUANTIFIABLE ADDITIONAL BENEFIT; RECOMMENDED
- KAFTRIO; ELEXACAFTOR & IVACAFTOR & TEZACAFTOR; VERTEX; CYSTIC FIBROSIS; Adults who have at least one non-class I mutation in the CFTR gene that is a gating mutation and not an F508del mutation.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- KAFTRIO; ELEXACAFTOR & IVACAFTOR & TEZACAFTOR; VERTEX; CYSTIC FIBROSIS; Adolescents who have at least one non-class I mutation in the CFTR gene that is a gating mutation and not an F508del mutation.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- KAFTRIO; ELEXACAFTOR & IVACAFTOR & TEZACAFTOR; VERTEX; CYSTIC FIBROSIS (PEDIATRIC); Children aged 2 years and older who have at least one non-class I mutation in the CFTR gene that is a gating mutation and not an F508del mutation.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- AUGTYRO; REPOTRECTINIB; BRISTOL MYERS SQUIBB; NSCLC (ROS1+); Adults with ROS1-positive, advanced, or metastatic cancer without prior treatment with a ROS1 inhibitor.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- LYTENAVA; BEVACIZUMAB; OUTLOOK THERAPEUTICS; AMD; Adults with neovascular (wet) disease.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED

HTAs: Canada

- COLUMVI; GLOFITAMAB; ROCHE; DIFFUSE LARGE B-CELL LYMPHOMA (COMBINATION); Adult patients who are not candidates for autologous stem cell transplant (ASCT).; CONDITIONALLY RECOMMENDED
- KEYTRUDA; PEMBROLIZUMAB; MERCK; CERVICAL CANCER (STAGE III & IV A) (CRT); Adult patients.; CONDITIONALLY RECOMMENDED
- CALQUENCE; ACALABRUTINIB; ASTRAZENECA; MANTLE CELL LYMPHOMA (COMBINATION); Adult patients who are previously untreated and who are ineligible for autologous stem cell transplant.; CONDITIONALLY RECOMMENDED
- SCEMBLIX; ASCIMINIB; NOVARTIS; CML (Ph+ NEWLY DIAGNOSED CHRONIC); Adult patients in chronic phase.; CONDITIONALLY RECOMMENDED
- OPDIVO; NIVOLUMAB; BRISTOL MYERS SQUIBB; MICROSATELLITE INSTABILITY-HIGH CANCER (COLORECTAL CANCER) (IPILIMUMAB); Adult patients with unresectable or metastatic microsatellite instability-high or mismatch repair deficient cancer.; CONDITIONALLY RECOMMENDED
- KEYTRUDA; PEMBROLIZUMAB; MERCK; HEAD AND NECK CANCER (PD-L1+); Adult patients with resectable locally advanced carcinoma whose tumours express PD-L1 [Combined Positive Score (CPS) ≥ 1].; CONDITIONALLY RECOMMENDED
- PERJETA; PERTUZUMAB; ROCHE; BREAST CANCER (NEOADJUVANT) (COMBINATION); Adult patients with early-stage HER2-positive carcinoma.; CONDITIONALLY RECOMMENDED
- YONDELIS; TRABECTEDIN; JOHNSON & JOHNSON INNOVATIVE MEDICINE; SOFT TISSUE SARCOMA; Adult patients with advanced unresectable or metastatic sarcoma.; CONDITIONALLY RECOMMENDED

- BLENREP; BELANTAMAB MAFODOTIN; GLAXOSMITHKLINE; MULTIPLE MYELOMA (RELAPSED OR REFRACTORY); Adult patients who have received at least 1 prior line of therapy, including lenalidomide.; CONDITIONALLY RECOMMENDED
- BLENREP; BELANTAMAB MAFODOTIN; GLAXOSMITHKLINE; MULTIPLE MYELOMA (RELAPSED OR REFRACTORY); Adult patients who have received at least 1 prior line of therapy.; CONDITIONALLY RECOMMENDED
- QUVIVIQ; DARIDOREXANT; IDORSIA; INSOMNIA; Adult patients who have difficulties with sleep onset and/or sleep maintenance.; NOT RECOMMENDED
- ELAHERE; MIRVETUXIMAB SORAVTANSINE; ABBVIE; OVARIAN CANCER (PLATINUM RESISTANT RECURRENT); Adult patients with FR-alpha–positive carcinoma who have received 1 to 3 prior systemic treatment regimens.; CONDITIONALLY RECOMMENDED

HTAs: Spain

- PIASKY; CROVALIMAB; ROCHE; PAROXYSMAL NOCTURNAL HEMOGLOBINURIA; Adult patients with hemolysis with clinical symptoms indicative of high disease activity.; RECOMMENDED
- PIASKY; CROVALIMAB; ROCHE; PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PEDIATRIC); Pediatric patients aged 12 years and older weighing 40 kg or more with hemolysis with clinical symptoms indicative of high disease activity.; RECOMMENDED
- PIASKY; CROVALIMAB; ROCHE; PAROXYSMAL NOCTURNAL HEMOGLOBINURIA; Adult patients who are clinically stable after having been treated with a complement C5 inhibitor for at least the last 6 months.; RECOMMENDED
- PIASKY; CROVALIMAB; ROCHE; PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PEDIATRIC); Pediatric patients aged 12 years and older who are clinically stable after having been treated with a complement C5 inhibitor for at least the last 6 months.; RECOMMENDED

HTAs: Brazil

- XALKORI; CRIZOTINIB; PFIZER; NSCLC (ALK+); Adult patients with advanced or metastatic ALK+ cancer.; NOT RECOMMENDED

Approvals: Brazil

- EPYZTEK; USTEKINUMAB; SAMSUNG BIOEPIS BR PHARMACEUTICAL LTDA; PSORIASIS, PSORIATIC ARTHRITIS, CROHN'S DISEASE AND ULCERATIVE COLITIS
- BLENREP; BELANTAMAB MAFODOTIN-BLMF; GLAXOSMITHKLINE BRASIL LTDA; MULTIPLE MYELOMA (RELAPSED OR REFRACTORY) (BORTEZOMIB AND DEXAMETHASONE) AND MULTIPLE MYELOMA (RELAPSED OR REFRACTORY) (POMALIDOMIDE AND DEXAMETHASONE)

Approvals: Europe

- BRINSUPRI; BRENSOCATIB; INSMED NETHERLANDS B.V.; BRONCHIECTASIS

Approvals: United States

- JASCAYD; NERANDOMILAST; BOEHRINGER INGELHEIM; IDIOPATHIC PULMONARY FIBROSIS
- EYDENZELT; AFLIBERCEPT; CELLTRION INC; AMD, MACULAR EDEMA FOLLOWING RETINAL VEIN OCCLUSION (RVO) , DME, DIABETIC RETINOPATHY (DR)
- LASIX ONYU; FUROSEMIDE; SQ INNOVATION, INC; EDEMA (HEART FAILURE)
- EPIOXA; RIBOFLAVIN5?-PHOSPHATE; GLAUKOS; KERATOCONUS
- JAVADIN; CLONIDINE HYDROCHLORIDE; AZURITY; HYPERTENSION
- BLENREP; BELANTAMAB MAFODOTIN-BLMF; GLAXOSMITHKLINE LLC; MULTIPLE MYELOMA (RELAPSED OR REFRACTORY) (BORTEZOMIB AND DEXAMETHASONE)
- CONTEPO; FOSFOMYCIN; MEITHEAL; UTI
- LYNKUET; ELINZANETANT; BAYER; VASOMOTOR SYMPTOMS
- EPYZTEK; USTEKINUMAB; SAMSUNG BIOEPIS BR PHARMACEUTICAL LTDA.; PSORIASIS, PSORIATIC ARTHRITIS, CROHN'S DISEASE AND ULCERATIVE COLITIS

Approvals: China

- BOFUWO; NAMILISTAT; BOEHRINGER INGELHEIM; PULMONARY FIBROSIS

Approvals: Canada

- LYVDELZI; SELADELPAR; GILEAD SCIENCES; PRIMARY BILIARY CHOLANGITIS
- LEQEMBI; LECANEMAB; BIOGEN INC.; ALZHEIMER'S DISEASE

Germany Post AMNOG Price Changes

PRODUCT GROUP	GENERIC NAME	DESCRIPTION	START DATE	MNF (EUR)	OLD MNF PRICE	MNF AMOUNT CHANGE	MNF (USD)	OLD MNF PRICE	MNF AMOUNT CHANGE	MNF % CHANGE
FILSPARI	SPARSENTAN	FILSPARI TABLETS 1 PACK 30 TABS 200 MG	10/01/25	3580.47	3980.00	-399.53	4143.32	4605.66	-462.34	-10.04%
FILSPARI	SPARSENTAN	FILSPARI TABLETS 1 PACK 30 TABS 400 MG	10/01/25	3580.47	3980.00	-399.53	4143.32	4605.66	-462.34	-10.04%
FINTEPLA	FENFLURAMINE	FINTEPLA ORAL SOLUTION 1 BOTTLE 120 ML 264 MG	10/01/25	785.82	794.96	-9.14	909.35	919.93	-10.58	-1.15%
FINTEPLA	FENFLURAMINE	FINTEPLA ORAL SOLUTION 1 BOTTLE 360 ML 792 MG	10/01/25	2357.47	2384.87	-27.40	2728.06	2759.77	-31.71	-1.15%
FINTEPLA	FENFLURAMINE	FINTEPLA ORAL SOLUTION 1 BOTTLE 60 ML 132 MG	10/01/25	392.91	397.48	-4.57	454.68	459.97	-5.29	-1.15%
ILUMETRI	TILDRAKIZUMAB	ILUMETRI INJECTION 1 PREFILLED PEN 1 ML 100 MG	10/01/25	2428.50	2540.72	-112.22	2810.26	2940.12	-129.86	-4.42%
ILUMETRI	TILDRAKIZUMAB	ILUMETRI INJECTION 1 PREFILLED SYRINGE 1 ML 100 MG	10/01/25	2428.50	2540.72	-112.22	2810.26	2940.12	-129.86	-4.42%
ILUMETRI	TILDRAKIZUMAB	ILUMETRI INJECTION 1 PREFILLED SYRINGE 2 ML 200 MG	10/01/25	2428.50	2540.72	-112.22	2810.26	2940.12	-129.86	-4.42%
KIMMTRAK	TEBENTAFUSP	KIMMTRAK INJECTION 1 VIAL 0.5 ML 100 MCG	10/01/25	9652.50	9900.00	-247.50	11169.87	11456.28	-286.41	-2.50%
KISQALI	RIBOCICLIB	KISQALI TABLETS 1 PACK 21 TABS 200 MG	10/01/25	1626.99	1628.00	-1.01	1882.75	1883.92	-1.17	-0.06%
REAGILA	CARIPRAZINE	REAGILA CAPSULES 1 PACK 98 CAPS 1.5 MG	10/15/25	195.00	198.00	-3.00	225.65	229.12	-3.47	-1.52%
REPATHA	EVOLOCUMAB	REPATHA INJECTION 2 PREFILLED PEN 1 ML 140 MG	10/01/25	334.48	341.31	-6.83	387.06	394.96	-7.90	-2.00%
REPATHA	EVOLOCUMAB	REPATHA INJECTION 6 PREFILLED PEN 1 ML 140 MG	10/01/25	1003.43	1023.92	-20.49	1161.17	1184.88	-23.71	-2.00%
SLENYTO	MELATONIN	SLENYTO EXTENDED RELEASE TABLETS 1 PACK 30 TABS 5 MG	10/15/25	97.49	97.56	-0.07	112.82	112.90	-0.08	-0.07%
SLENYTO	MELATONIN	SLENYTO EXTENDED RELEASE TABLETS 1 PACK 60 TABS 1 MG	10/15/25	37.49	37.56	-0.07	43.38	43.46	-0.08	-0.19%
ULTOMIRIS	RAVULIZUMAB	ULTOMIRIS INFUSION 1 VIAL 11 ML 1100 MG	10/01/25	13386.95	13639.27	-252.32	15491.38	15783.36	-291.98	-1.85%
ULTOMIRIS	RAVULIZUMAB	ULTOMIRIS INFUSION 1 VIAL 3 ML 300 MG	10/01/25	3650.99	3719.80	-68.81	4224.93-	4304.56	-79.63	-1.85%
VEOZA	FEZOLINETANT	VEOZA TABLETS 1 PACK 100 TABS 45 MG	10/15/25	160.11	200.00	-39.89	185.28	231.44	-46.16	-19.95%
VEOZA	FEZOLINETANT	VEOZA TABLETS 1 PACK 30 TABS 45 MG	10/15/25	48.03	60.00	-11.97	55.58	69.43	-13.85	-19.95%
VOYDEYA	DANICOPAN	VOYDEYA TABLETS 1 KIT 180 TABS 100 MG	10/01/25	8169.71	9077.45	-907.74	9453.99	10504.43	-1050.44	-10.00%
VOYDEYA	DANICOPAN	VOYDEYA TABLETS 1 KIT 90 TABS 150 MG	10/01/25	6127.29	6808.09	-680.80	7090.50	7878.32	-787.82	-10.00%
XOSPATA	GILTERITINIB	XOSPATA TABLETS 1 PACK 84 TABS 40 MG	10/01/25	15688.00	12550.40	+3137.60	18154.15	14523.32	+3630.83	+25.00%

Drug Launches: Europe & U.S.

COUNTRY	GENERIC NAME	PRODUCT GROUP	COMPANY	INDICATION	THERAPEUTIC AREAS	PRODUCT APPROVAL DATE (MM-DD-YYYY)	START DATE (LAUNCH DATE) (MM-DD-YYYY)
FRANCE	PEGFILGRASTIM	DYRUPEG	ARROW	PREVENTION OF INFECTION (FEBRILE NEUTROPENIA)	ONCOLOGY	03/28/2025	10/15/2025
FRANCE	FILGRASTIM	ZEFYLTI	ARROW	PREVENTION OF INFECTION (FEBRILE NEUTROPENIA)	ONCOLOGY	02/12/2025	10/16/2025
GERMANY	SEBETRALSTAT	EKTERLY	KALVISTA PHARMACEUTICALS	HEREDITARY ANGIOEDEMA	BLOOD AND BLOOD FORMING ORGANS	09/17/2025	10/15/2025
UNITED KINGDOM	SERPLULIMAB	HETRONIFLY	ACCORD	SMALL CELL LUNG CANCER (COMBINATION)	ONCOLOGY	06/20/2025	10/01/2025
UNITED KINGDOM	TEPROTUMUMAB	TEPEZZA	AMGEN	THYROID EYE DISEASE	IMMUNOSUPPRESSANTS	05/07/2025	10/22/2025
UNITED STATES	NALMEFENE	ZURNAI	PURDUE	OPIOID OVERDOSE	NEUROLOGY	08/07/2024	10/06/2025

Price Changes: Europe & U.S.

COUNTRY	GENERIC NAME	PRODUCT GROUP	COMPANY	THERAPEUTIC AREA	AVG. PRICE CHANGE ALL SKU	FIRST PRICING DATE (MM-DD-YYYY)
FRANCE	RIOCIGUAT	ADEMPAS	MSD	CVS	-42.44%	01/15/2015
FRANCE	PNEUMOCOCCUS, PURIFIED POLYSACCHARIDES ANTIGEN CONJUGATED	PREVENAR 20	PFIZER	VACCINES	-2.99%	03/07/2024
SPAIN	DIETHYLAMINE & SALICYLIC ACID	ALGESAL	STADA	DERMATOLOGY	3.99%	10/01/2018
SPAIN	GUANFACINE	INTUNIV	TAKEDA	CVS	-42.99%	01/01/2017
UNITED KINGDOM	BUTYLSCOPOLAMINE	BUSCOPAN	OPELLA HEALTHCARE	GASTROENTEROLOGY	2.70%	11/01/2004
UNITED STATES	SUTIMLIMAB	ENJAYMO	RECORDATI	IMMUNOSUPPRESSANTS	3.20%	02/04/2022
UNITED STATES	FLUORESCEIN	FLUORESCITE	ALCON	OPHTHALMOLOGY	-12.95%	02/01/1988
UNITED STATES	CEMIPLIMAB	LIBTAYO	REGENERON PHARMACEUTICALS	ONCOLOGY	3.75%	09/28/2018
UNITED STATES	PEXIDARTINIB	TURALIO	DAIICHI SANKYO	ONCOLOGY	3.00%	08/02/2019

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