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INSIGHTS Newsletter

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Labour's Landslide UK General Election Victory Brings Bold Plans for the NHS & Healthcare

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What Does the New EU Parliament Have in Store for Pharma?

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Drug Manufacturers Face Two "Tough on Pharma" Candidates in 2024 U.S. Presidential Election

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NAVLIN DAILY
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Editor's Note

It's not often that the UK, U.S. and Europe all experience potential political change within a few months of one another. The recent European Parliament elections and Labour's landslide victory in the UK have set the stage, while the U.S. gears up for its own pivotal election.

We took this issue as an opportunity to delve into the results of the voting in the UK and Europe, discussing the outcomes and potential implications for market access. Across the pond in the U.S., while we can't predict the future, we give you the lowdown on where the current candidates stand on healthcare and drug pricing, offering a comprehensive overview of what the future may hold, whichever party comes out on top.

Shifting our gaze beyond the major players, don't miss our critical update on Saudi Arabia's move toward mandatory pharmacoeconomic assessments.

Happy reading!

Anna Smith

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NAVLIN Insight: Labour's Landslide UK General Election Victory Brings Bold Plans for the NHS & Healthcare

Luke Hannaford

NAVLIN BRIEF:

- Labour's election victory ends 14 years of Conservative rule, with the party promising significant improvements to the NHS such as reducing waiting times
- Additionally, Labour aims to improve access to medicines by streamlining regulatory processes, reducing bureaucracy, and enhancing the adoption of innovative technologies within the NHS
- Despite these ambitious plans, organizations like the King's Fund question the clarity of spending implications for health and care budgets, leaving the long-term success of Labour's commitments uncertain

THE DETAILS

LONDON, United Kingdom – The Labour party won a landslide victory in the UK general election, putting an end to 14 years of Conservative rule, but what do Labour's policies aim to bring to improve the healthcare system?

Prepared by the Labour party, the King's Speech revealed a bold vision for the future of the National Health Service (NHS) and broader public health initiatives.

"My government will improve the National Health Service as a service for all, providing care on the basis of need regardless of the ability to pay," King Charles read.

Addressing NHS waiting times, Labour underscores that this is the party's "immediate priority." Labour has committed to meeting NHS performance standards within the first five years of entering government, including that patients should expect to wait no longer than 18 weeks from referral for consultant-led treatment of non-urgent health conditions.

Medicines & Vaccines Access

While the King's speech did not highlight Labour's "Build an NHS Fit for the Future," the plan sets out measures such as:

- A plan for procurement, adoption and spread of new technologies: so, innovators have a clearer route to get their product into the NHS, identifying which goods and services should be procured centrally at volume, to get the best value for the taxpayer, versus where a local approach works better
- A better mechanism for accountability of commissioners: Intergrated Care Systems are obligated by law to "foster and deploy research and innovations." Work with the NHS to define what this means in practice and how to better hold them to account for delivery, whilst allowing for greater flexibility where appropriate
- An approach to identify unnecessary bureaucracy and reduce it: so, NHS Trust Drugs and Therapeutic Committees do not unnecessarily re-evaluate products that have already been shown to be clinically and cost-effective by the National Institute for Health and Care Excellence (NICE)

- Reform the incentives structure for adoption of technology: using payment mechanisms that help teams implement new technologies successfully and quickly, whilst phasing out older options. Work with the Care Quality Commission to ensure regulation involves speedy adoption of new technology: so that regulatory assessments of healthcare providers involve adoption of innovative technology to deliver improved care
- Better horizon scanning: for emerging treatments, like new, revolutionary drugs for dementia, so that we can prioritize and prepare the NHS to implement at speed

In contrast if the Conservative party had maintained power, they would have removed the NHS Budget Impact Test to help improve access to medicines.

Additionally, the Conservatives would have aligned NHS England's cost-effectiveness thresholds for new medicine indications with those used by NICE.

Life Sciences

Labour also hopes to boost the economy by marrying the health and social care system with the life sciences and med tech ecosystem, as AstraZeneca, one of the UK's drugmakers recent financial and operational results highlight the growing demand for innovative medicines.

The company reported a total revenue of $25,617 million for H1 2024, reflecting an 18% increase, driven by strong performance in oncology and biopharmaceuticals. Notably worldwide sales of Enhertu (trastuzumab deruxtecan) increased by 46% standing at $932 million. Additionally, Tagrisso (osimertinib), Imfinzi (durvalumab), and Lynparza (olaparib) contributed significantly to growth.

Commenting on the financial results, Pascal Soriot, Chief Executive Officer, AstraZeneca, said: "In the year to date we have continued to make encouraging progress with several disruptive technologies, including antibody drug conjugates, bispecifics, cell and gene therapies, radioconjugates, and weight management medicines, all of which have the potential to drive our growth beyond 2030."

However, Soriot called on the new Labour government to reassess its approach to funding of new medicines, after the National Institute for Care and Excellence (Nice) decided in March that Enhertu did not provide value for money.

Currently, HER2-low breast cancer is managed using treatments established for HER2-negative breast cancer. NICE's committee's rationale concluded that HER2-low is a subgroup of what was previously classified as HER2-negative cancer, making treatment options for HER2-negative metastatic breast cancer after chemotherapy relevant to this evaluation.

The primary evidence supporting Enhertu originates from the DESTINY-Breast04 clinical trial. This clinical trial data demonstrates that Enhertu prolongs overall survival and extends the duration before cancer progression compared to chemotherapy treatments typically employed for HER2-negative breast cancer.

Despite being the first authorized treatment option for individuals dealing with HER2-low metastatic or unresectable breast cancer, NICE concluded that uncertainties within the company's economic model have led to cost-effectiveness estimates that were considered above the range NICE considers an acceptable use of NHS resources despite taking into account the severity of the condition and its impact on quality and life expectancy.

"I hope the new government will take a new look at the way medicines are being assessed," Soriot told journalists on Thursday, while declining to say if he would lower prices of the medicine to increase access.

The list price for Enhertu is £1,455 per vial, each containing 100 mg of powder for concentrate for solution for infusion, excluding VAT; the company has a commercial arrangement in place that would have made the drug available to the NHS at a confidential discount, had it been recommended. The treatment, however, is available in Scotland.

Meanwhile, the Association of the British Pharmaceutical Industry's (ABPI) Chief Executive, Richard Torbett, agrees with Labour's message that it is right to think about the health system as more than just a public service.

"With the right outlook, our health system can become an active partner for life science innovation and discovery. It can do more to prevent ill health, through the use of new vaccines and preventative medicines, while also getting people healthy and back to work by removing persistent inequality of access to the most effective treatments," adds Torbett.

However, the ABPI outlines several measures that it would like to see from Labour in its first 100 days in government, which include:

- The launch of the Life Sciences Manufacturing Capital Grants Facility
- The rapid passing of outstanding UK clinical trials legislation to enhance the UK's attractiveness for inward investment, including into research within the NHS
- The urgent appointment of a new Chair and Chief Executive to the Medicines and Healthcare products Regulatory Agency (MHRA)
- Increase the commercial flexibility in the NHS England Commercial Framework for New Medicines to remove barriers for companies to launch new medicines and indications so that NHS patients can access the latest innovative medicines
- Support NICE to rapidly review the 'severity modifier' used in medicine appraisals, as a NICE board meeting revealed that weightings of both 1.7 and 1.2 have been applied in multiple topics. However, wider use of the 1.2 severity weighting had been anticipated

- Re-establish a cross-government and industry working group to examine progress in implementing vaccination-related policy
- Review and respond to outstanding recommendations made for the National Immunization Program by the Joint Committee on Vaccination & Immunization (JCVI)

Overall, Labour's comprehensive plans for the NHS and healthcare system promise significant improvements and access to medicines. However, only time will tell whether the party's commitments hold true, as organizations such as the King's Fund question Labour's manifesto, noting that there is no "clarity on the spending implications for health and care budgets."

NAVLIN Insight: What Does the New EU Parliament Have in Store for Pharma?

Anna Smith

NAVLIN BRIEF:

- With the composition of the European Parliament being slowly but surely pieced together after the recent election, the results could have significant impact on health policies, such as the European Health Union, Pharmaceutical Strategy for Europe, and the European Health Data Space (EHDS)
- Last month, the 2024 European Parliament elections took place and resulted in 720 members of parliament being elected, 15 more than in the previous elections - as expected in polls, right-wing and far-right parties made significant gains, though not quite to the extent anticipated
- The revision of the pharmaceutical legislation is likely the most important piece of healthcare-related legislation that the incumbent Parliament has to address. Additionally, the recently published guidelines indicate that the incumbent Commission, helmed again by Ursula von der Leyen, will focus on the Critical Medicines Act, building on H.E.R.A.,and ensuring European health union

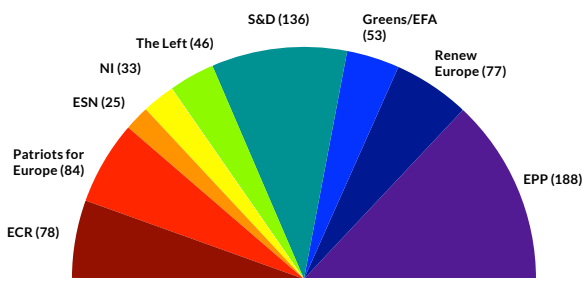
THE DETAILS

BRUSSELS, Belgium – Despite the significant wins and losses, no single bloc emerged with an overall majority in the European Parliament and centrist parties began working to form a coalition to support a second term for incumbent President of the Commission, Ursula von der Leyen.

The European People's Party (EPP) remained the party with the most seats, but two areas where the right prevailed strongly were France and Italy. In Italy, Prime Minister Giorgia Meloni saw her Brothers of Italy party consolidate its position with 28.7% of the vote, and in France, President Emmanuel Macron's Renaissance Party won just 14.6% of the vote, while Rassemblement National won 31.3% of the vote.

European Parliament 2024-2029

Constitutive session



720 Seats

Source: https://results.elections.europa.eu/en/index.html

Healthcare in the EU

The aftermath has brought into focus the implications for healthcare policies. Rare Diseases Europe (EURORDIS) recently noted that newly elected MEPs will soon convene to elect key officials and set priorities that will guide EU health policy for the coming years. The European Parliament has already elected Ursula von der Leyen as President of the European Commission, marking her second term after winning 401 votes in favor.

Under her first term of leadership, the EU pushed through an unprecedented amount of healthcare work, backed by record funding.

What's in the Manifestos?

Von der Leyen's party, theEPP, hold 188 of the final 720 seats. Their manifesto provides several insights targeting public health, including a mention of an EU Health Union, and several mentions of wellbeing. Equity is developed in several aspects, in terms of health, gender, age, but also territorial equity. Particularly, funding for health research is extensively covered. The manifesto also provides several elements relevant to pandemic and crisis preparedness.

Key proposals include:

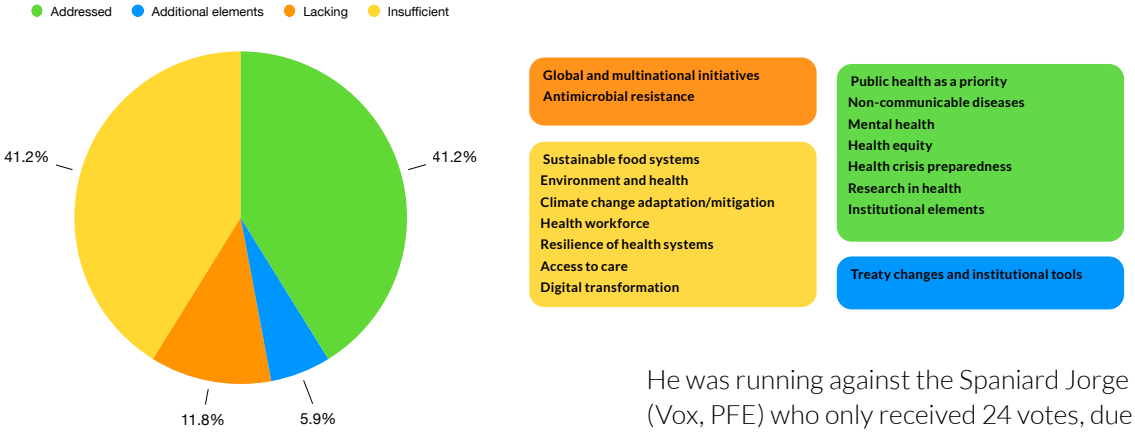
- European plan to address Alzheimer's disease, dementia and Parkinson's disease

- European Cardiovascular Health Plan
- Implementation of Europe's Beating Cancer Plan

However, the EPP manifesto does not address the question of antimicrobial resistance (AMR), nor does it mention the concept of One Health. Although mentioning on several occasions the role of the EU on the global stage, the manifesto does not address the current commitments of the EU on global and multilateral initiatives. Current industry priorities are also omitted, such as the Pharma Package, and the European Health Data Space (EHDS).

Assessing content related to health

by number of topics



Disclaimer: this visual reflects the coverage of the 16 topics listed in the analysis. Some of the topics comprise more elements than others

S&D

S&D, the parliamentary group of the Party of European Socialists (PES), is the second largest group in the European Parliament. In the elections, the party ended up with 136 seats. The PES manifesto hints at providing importance to public health, with a call for a stronger Health Union. In terms of access to care, the manifesto commits to quality healthcare, as well as calling for security of supply in medicines, and "fair pricing" to prevent shortages. It also refers to research, regarding anti-microbial resistance (AMR), vaccines and rare medicines.

However, it does not address the biggest health burden in the EU: non-communicable diseases (NCDs). Similar to the EPP manifesto, there is no mention made of the European Health Data Space, nor the Pharma Package.

ECR & Renew Europe

The European Conservatives and Reformists Party (ECR) and Renew Europe won 78 and 77 seats, respectively. While the ECR supports the generic drugs sector, there's also a hint of antagonism to Big Pharma — the home of the innovative, and more costly, medicines industry.

The ECR wants to see more affordable therapies, while pushing for "collaborative research on medicines" such as through the EU's Horizon Europe funding program, according to Michael Strauss, a spokesperson for the right-wing group. He added, "We will seek to strengthen the system whereby publicly funded research should lead to open knowledge."

Makeup of Health Committees

MEPs have elected Italian social democrat Antonio Decaro as chair of the European Parliament's influential committee on environment, public health and food safety (ENVI), while the Patriots for Europe (PfE) group was denied the last of four vice-chair positions after the EPP's coordinator for the ENVI committee, as it is known - German MEP Peter Liese - put forward Hungarian doctor András Kulja, who was backed by 64 members in a secret vote.

He was running against the Spaniard Jorge Buxadé Villalba (Vox, PFE) who only received 24 votes, due to the "cordon sanitaire". The other vice-presidents are Esther Herranz García (Spain, EPP), Pietro Fiocchi (Italy, CRE) and Anja Hazekamp (Netherlands, The Left).

Looking to the Term Ahead

The revision of the pharmaceutical legislation is likely the most important piece of healthcare-related legislation that the incumbent Parliament has to contend with.

The previous Presidency held by Belgium, which ended at the end of June, made significant progress with the European Health Union framework. However, key issues remain unresolved, particularly related to pharmaceutical legislation.

The legislation is not expected to be negotiated until 2026 and will likely not be in effect until 2028. The main concern for policymakers now is aligning these changes with the goal of enhancing Europe's competitiveness and resilience.

A key feature of the package review is AMR; during the last term, the Commission set some important stakes regarding the fight against AMR, and the effort needs to be continued. Another important development is the approval of the European Health Data Space Regulation (EHDS), which is part of the broader European data strategy.

The political guidelines for 2024-2029 indicate that, among other priorities, the Commission helmed by von der Leyen will focus on:

- Critical Medicines Act: The document highlights the introduction of a Critical Medicines Act aimed at reducing dependencies on critical medicines and ingredients. This act will address shortages of medical devices and medicines, including antibiotics, insulin, and painkillers, particularly focusing on products with limited suppliers.

- European Health Union: The goal is to complete the European Health Union by diversifying supply chains, ensuring access to advanced treatments, strengthening health systems, and maintaining strategic inventories of key medicines. The focus will also include combating AMR.

- Research and Innovation: Increased investment in research, particularly in strategic priorities, groundbreaking research, and disruptive innovation, will be a priority. The European Research Council and the European Innovation Council will be expanded to support this.

- Public-Private Partnerships: Emphasis is placed on creating public-private partnerships to provide the necessary infrastructure and laboratories for researchers, helping to develop new ideas and innovations in the health sector.

- Preventive health: In particular for mental health, including at work, and cardiovascular diseases, as well as on treatments for degenerative illnesses and research on autism. This will build on the successful model of the Beating Cancer Plan.

- Building on H.E.R.A: we will present a new strategy to support medical countermeasures against public health threats, such as those linked to CBRN security, including joint procurement and stockpiling.

In response to the guidelines, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has "welcomed" the ambition, adding: "The dedicated life sciences strategy, which includes plans for a new Biotech Act, is an important part of the wider drive to boost European competitiveness over the next five years.

NAVLIN Insight: Drug Manufacturers Face Two "Tough on Pharma" Candidates in 2024 U.S. Presidential Election

Raechel Pusateri

NAVLIN BRIEF:

- Although drug pricing has not been a major campaign issue in the 2024 U.S. presidential election so far, drug manufacturers likely face another four years of "tough-on-pharma" policy regardless of the outcome
- Both Donald Trump, the Republican nominee, and Kamala Harris, the likely Democratic nominee, have a history of going after the pharmaceutical industry to control drug prices in the U.S. If he wins, Trump has indicated that he intends to revive his "Most Favored Nation" policy, which would allow the U.S. to pay the lowest price paid among other wealthy nations that are part of the Organization for Economic Co-operation and Development (OECD) for some Medicare-covered drugs. Harris, meanwhile, has been a vocal proponent of the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program and "march-in rights"
- In Congress, there are several bills expected to gain momentum after the November election. These include policies to reform the pharmacy benefit manager (PBM) industry, legislation intended to end U.S. federal contracts and partnerships with China-based biotech companies, and measures to reform the 340B Drug Pricing Program

THE DETAILS

WASHINGTON, DC, United States – Drug pricing appears to have taken a back seat in the upcoming 2024 U.S. presidential election compared to 2020 and 2016; however, the outcomes of the fast-approaching contest could still have major implications for the pharmaceutical industry.

Former President Donald Trump is returning as the Republican nominee for this year's election and has selected Ohio state senator JD Vance as his running mate.

Meanwhile, in a recent shake-up, President Joe Biden has decided to drop out of the race, leaving the Democratic nomination up for grabs. At this point in the election cycle, it appears likely that the nomination will go to current Vice President Kamala Harris.

In the past, both Donald Trump and Kamala Harris have targeted pharmaceutical companies in a bid to address drug prices in the U.S., so manufacturers are unlikely to catch a break regardless of who is elected in the fall. However, Trump and Harris have explored different approaches to reining in the cost of prescription medications. A breakdown of the policies both lawmakers have proposed over the years is below:

Donald Trump and JD Vance

In a departure from previous elections, Donald Trump's 2024 campaign has released few details regarding the former president's health policy goals or positions for the upcoming election. Currently, Trump's platform on health reads:

"Healthcare and prescription drug costs are out of control. Republicans will increase Transparency, promote Choice and Competition, and expand access to new Affordable Healthcare and prescription drug options. We will protect Medicare, and ensure Seniors receive the care they need without being burdened by excessive costs."

Historically, however, Trump has held a strong interest in addressing prescription drug prices and improving transparency throughout the pharmaceutical industry.

During his last presidency, the Trump Administration:

- Established a voluntary model allowing participating Medicare Part D plans to limit monthly insulin costs to $35
- Created a new pathway to allow states to import prescription drugs from Canada
- Proposed a "Most Favored Nation" (MFN) system of international reference prices that stipulated that the U.S. would pay the lowest price paid among other wealthy nations that are part of the Organization for Economic Co-operation and Development (OECD) for some Medicare-covered drugs. Trump originally campaigned on Medicare drug price negotiations leading up to the 2016 election, but discarded this approach in favor of the MFN policy. Ultimately, the MFN proposal was blocked by court action and later rescinded
- Proposed a rule requiring drug manufacturers to disclose drug prices in television ads, which was also blocked by court ruling
- Proposed to eliminate drug rebates in Medicare Part D and pass discounts on directly to patients at the

pharmacy counter. However, the implementation of this policy has been delayed until 2032

- Proposed several changes to the Medicare Part D benefit design, including a cap on out-of-pocket costs and weaker formulary standards

Interestingly, while the Trump campaign has been relatively silent on drug pricing over the past several months, in June 2023, the former president released a video promising to sign an executive order to revive the MFN rule on "day one" if reelected to the Oval Office. In the video, Trump claims that he was "the only president in modern times who ever took on Big Pharma" and that President Biden canceled his "tough-on-pharma policies the moment he had a chance."

Trump's new running mate, JD Vance, has also expressed a desire to address prescription drug costs and takes a more populist approach to health care and big business compared to traditional GOP lawmakers.

Although many conservative policymakers oppose the Inflation Reduction Act's (IRA) drug pricing provisions, calling Medicare negotiation a form of "government price controls," Vance has vocalized his support for such negotiation in the past. The lawmaker has also promoted importation as a measure to reduce drug prices in the U.S.

JD Vance also breaks from the traditional GOP stance on the Affordable Care Act (ACA), recognizing that key parts of the law, like protections for pre-existing conditions, enjoy widespread public support.

Kamala Harris

Kamala Harris, who is expected to secure the Democratic nomination after President Joe Biden ended his reelection campaign, is also no friend to the pharmaceutical industry.

As California's attorney general, Harris demonstrated a strong interest in addressing anticompetitive behavior in the health care industry—including among pharmaceutical companies—as well as in bringing down the cost of care. She is also a strong supporter of the Inflation Reduction Act's (IRA's) drug price negotiation provision and could pursue President Biden's recent calls to expand the law to allow Medicare to negotiate prices for at least 50 drugs each year.

Looking at Harris's former positions, it seems likely that she could take an even tougher stance on drug prices than President Biden. As a presidential candidate in 2019, Harris supported a plan allowing the U.S. Department of Health and Human Services (HHS) to set new price caps for all drugs sold in the U.S. based on prices charged in other developed countries for the same medications.

Harris has also been a proponent of using "march-in rights" under the Bayh-Dole Act, which allow a government agency that funds private research to require a company to license its patent to another party under certain conditions—such as when action is necessary to alleviate health or safety needs or when an invention's benefits are not available to the public on reasonable terms.

Although the U.S. government has never exercised its march-in rights, in recent years, some Democratic lawmakers have argued in favor of exploring the authority as a method of addressing drug prices, claiming that a product's price can determine whether it is reasonably available to the public. In December of 2023, the Biden-Harris Administration released new draft guidance outlining how the U.S. government could regulate drug prices using Bayh-Dole.

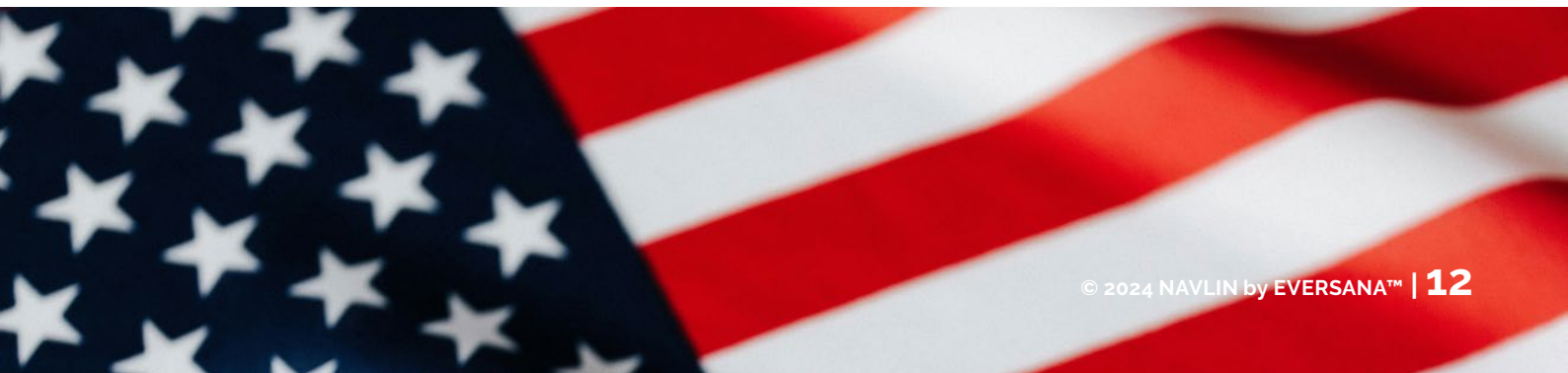
Congressional Election Results

The U.S. presidential election is not the only race that matters this fall. The extent of the next elected president's influence on policy will hinge on which party takes control of the House and Senate following the elections. Early predictions suggest it is unlikely that either party will take both Chambers of Congress in 2024, so passing partisan or controversial legislation (like expanding or repealing the IRA's drug pricing provisions) may remain a challenging endeavor.

Even without these logistical roadblocks, pharmaceutical companies have enjoyed a slight reprieve from Congressional scrutiny over the past several months, with lawmakers homing in on the role pharmacy benefit managers (PBMs) play in driving up prescription drug prices. It seems likely that lawmakers will continue to focus their attention on these middlemen for the time being when it comes to drug pricing.

However, there are several pharma-related pieces of legislation poised to gain momentum after the November elections. These include the BIOSECURE Act, which aims to end U.S. federal contracts and partnerships with China-based biotech companies, including WuXi AppTec, Complete Genomics, Beijing Genomics Institute (BGI), and MGI. According to Speaker of the House Mike Johnson (R-LA), the House is slated to vote on the bill in the fall.

Other bills that could advance after the election include reforms to the 340B Drug Pricing Program and the U.S. patent system.



MHRA Backs Wegovy for Cardiovascular Risk via IRP

Date: 24 Jul 2024 | #WEGOVY #REDUCE THE RISK OF MAJOR ADVERSE CARDIOVASCULAR EVENTS #DIABETOLOGY #NOVO NORDISK #EUROPE #UNITED KINGDOM #cardiovascular disease #Novo Nordisk #approval #Wegovy #MHRA #obesity

NAVLIN BRIEF:

- The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has authorized a new use of Novo Nordisk's Wegovy (semaglutide): to mitigate the risk of serious heart conditions among obese adults with established heart disease, making it the first weight loss medication in the UK cleared for cardiovascular event prevention
- The new approval allows for wider use of Wegovy to prevent cardiovascular incidents, including heart attacks and strokes, based on clinical data indicating a 20% fall in major adverse heart events compared to placebo
- While the National Institute for Health and Care Excellence (NICE) has yet to endorse this use of Wegovy for this inducation, NHS England's national medical director, Professor Sir Stephen Powis, has a positive outlook on the decision

THE DETAILS

LONDON, United Kingdom—The Medicines and Healthcare products Regulatory Agency (MHRA) has granted approval for a new use of Novo Nordisk's Wegovy (semaglutide) to reduce the risk of serious heart problems in overweight and obese adults with established cardiovascular disease.

The decision makes Wegovy – which was already approved for weight management and obesity treatment – the first weight loss drug in the UK approved for the prevention of cardiovascular events.

The new approval expands its use to prevent cardiovascular events such as cardiovascular death, non-fatal heart attack, and non-fatal stroke in individuals with a Body Mass Index (BMI) of 27 kg/m^2 or higher. This approval is backed by data from a comprehensive clinical study indicating a 20% reduction in major adverse cardiovascular events for those on Wegovy compared to a placebo.

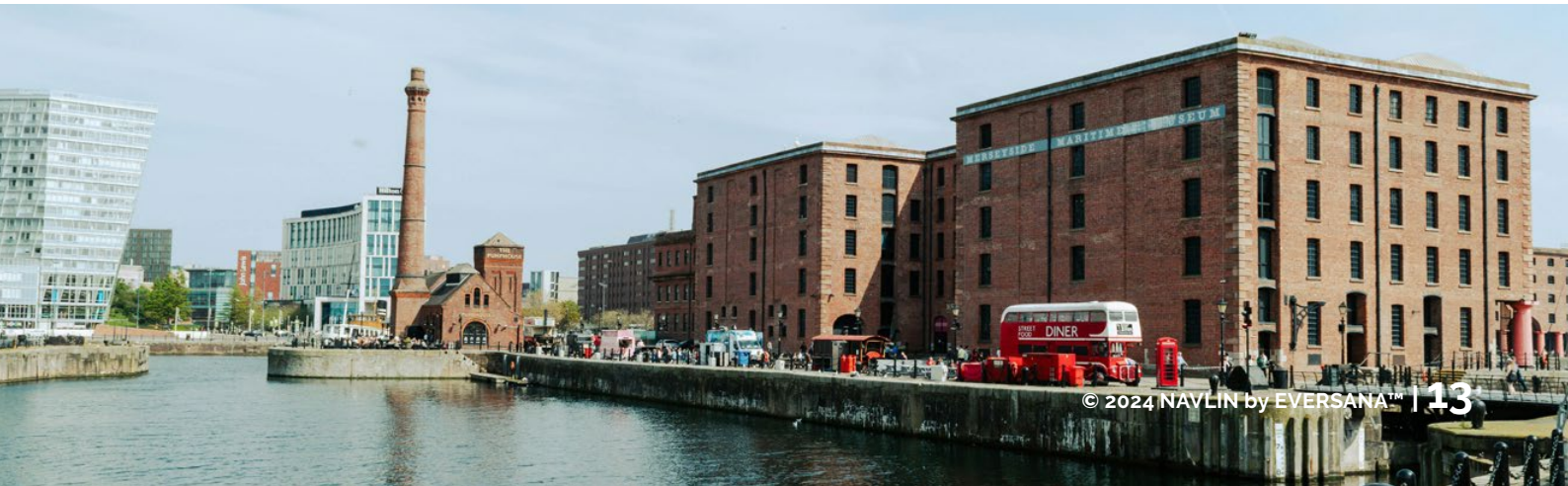
On news of the approval, Chief Scientific and Medical Officer at the British Heart Foundation, Professor Bryan Williams, reminded, "Nearly two thirds of adults in England are living with excess weight or obesity. Those that also have an established cardiovascular disease live with a very high risk that a serious event like a heart attack or stroke could happen."

He added, "Several recent studies have shown us that semaglutide is an effective tool that can improve the quality of life for those with cardiovascular disease, including by lowering the risk of serious cardiac events.

"It is important that people using the drug to lose weight and improve their health are given the support they need from healthcare professionals to maintain these improvements long into the future."

The National Institute for Health and Care Excellence (NICE) has yet to recommend this use for the product, but Professor Sir Stephen Powis, national medical director for NHS England, is feeling positive, noting it can "help reduce cardiovascular risks for high-risk patients, potentially preventing heart attacks and strokes, and giving more people the chance of a healthier future".

The approval was made with the support of the International Recognition Procedure (IRP), which aims to accelerate the assessment of new medicines by leveraging the expertise of trusted regulatory partners.



Vertex Confirms UK-Wide Access for CF Portfolio

Date: 25 Jul 2024 | #SYMKEVI #TRIKAFTA #ORKAMBI #KAFTRIO #CYSTIC FIBROSIS #CYSTIC FIBROSIS (PEDIATRIC) #RESPIRATORY #VERTEX #EUROPE #UNITED KINGDOM #Vertex #long-term reimbursement deals #Symkevi #cystic fibrosis #UK #Kaftrio #NICE #Orkambi

NAVLIN BRIEF:

- Following a long-term deal struck in England, Vertex Pharmaceuticals has confirmed the signing of similar deals in Scotland, Wales and Norther Ireland, making the company's cystic fibrosis (CF) medicines permanently available for children and adults in the whole of the UK
- The extended long-term reimbursement deals will ensure access to the company's whole CF portfolio, including Kaftrio (ivacaftor/tezacaftor/elexacaftor), Symkevi (tezacaftor/ivacaftor) and Orkambi (lumacaftor/ivacaftor) for all existing and future eligible patients in Scotland, Wales and Northern Ireland
- The final outcome ends years of issues between Vertex and the UK; David Ramsden, Chief Executive of Cystic Fibrosis Trust, noted the charity is "delighted that Northern Ireland and Wales have now formalised agreement for permanent access for the modulator therapies, helping to ensure that everyone now, and in the future, can access these life-changing medicines."

THE DETAILS

EDINBURGH, Scotland – Following a long-term deal struck in England, Vertex Pharmaceuticals has confirmed the signing of deals in Scotland, Wales and Northern Ireland, making the company's cystic fibrosis (CF) medicines permanently available for children and adults in the whole of the UK.

The extended long-term reimbursement deals will ensure access to the company's whole CF portfolio, including Kaftrio (ivacaftor/tezacaftor/elexacaftor), Symkevi (tezacaftor/ivacaftor) and Orkambi (lumacaftor/ivacaftor) for all existing and future eligiblße patients in Scotland, Wales and Northern Ireland.

The final outcome ends years of issues between Vertex and NICE; The Boston-headquartered biotech struggled to bring Orkambi to the market in England for a number of years, initially refusing to drop its asking price of £104,000 per patient per year to make it more affordable to the NHS. Eventually, an agreement was struck in 2019, and a binding condition of the deal was that Vertex had to submit its full portfolio over the coming four years, including Kaftrio. Several organizations, such as the Cystic Fibrosis Trust and various CF patient associations, played crucial roles in making these first steps happen.

In November last year, NICE released a first draft guidance consultation report rejecting the portfolio, noting that the cost-effectiveness estimates for these three drugs "significantly exceeded" the range considered acceptable by NICE. However, in the final draft guidance released last week, NICE conceded that given the "severity of CF and its effects of quality and length of life," the cost-effectiveness estimates for Kaftrio, Symkevi and Orkambi now fell within its threshold of acceptable use of NHS resources. The UK charity Cystic Fibrosis Trust stated, "It is one of the first times this has been used for non-cancer medicines, recognising the severity of CF."

NICE's decision paved the way for the other countries in the UK to sign their long-term reimbursement deals.

Joanna Barrett, Trustee of Cystic Fibrosis Trust, from Scotland, said: "It's fantastic news that all eligible people with cystic fibrosis in Scotland are guaranteed access to modulator therapies, now and in the future. Treatments like Kaftrio have made an enormous difference to the lives of people with CF and while there's more to do to make sure all people with CF can live a life unlimited, this is an enormously important milestone in making that happen."

David Ramsden, Chief Executive of Cystic Fibrosis Trust, noted the charity is "delighted that Northern Ireland and Wales have now formalised agreement for permanent access for the modulator therapies, helping to ensure that everyone now, and in the future, can access these life-changing medicines."

The Future for Vertex and the UK

Vertex is currently also in talks with NHS England and NICE regarding its next-generation triple combination CF treatment, dubbed vanza triple. In data released earlier this year, treatment with the once-daily vanza triple CFTR modulator regimen met all primary and key secondary endpoints in two randomized controlled trials in people with CF ages 12 years and older.

Vertex plans to file for approval with global regulators for people with CF ages 6 years and older by mid-2024.

NICE Confirms Hemgenix Recommendation as Part of OBA Under 2024 VPAG

Date: 11 Jul 2024 | #HEMGENIX #HAEMOPHILIA B #BLOOD AND BLOOD FORMING ORGANS #CSL BEHRING #EUROPE #UNITED KINGDOM #VPAGIMF #OBA

NAVLIN BRIEF:

- The National Institute for Health and Care Excellence (NICE) has disclosed that the recommendation of CSL Behring's Hemgenix (etranacogene dezaparvovec) is part of the first pilot for the outcomes-based agreements (OBA) under the commitments in the 2024 Voluntary Scheme for Pricing, Access, and Growth (VPAG)
- As per the 2024 VPAG for commercial agreements, NHS England recognizes there will be some cases where additional support is needed for introducing advanced therapy medicinal products (ATMPs) into the NHS, including innovative payment models. NHS England commits to delivering two innovative payment model pilots to explore the practicalities of OBA's for ATMPs
- The Institute issued final draft guidance last month recommending the drug via managed access for treating moderately severe to severe hemophilia B (congenital factor IX [FIX] deficiency) in adults without anti-FIX antibodies

THE DETAILS

LONDON, United Kingdom — As reported at the end of last month, NICE issued final draft guidance recommending CSL Behring's Hemgenix for the treatment of moderately severe to severe hemophilia B (congenital factor IX [FIX] deficiency) in adults without anti-FIX antibodies.

Now, the Institute has confirmed that the treatment is the first to be recommended via its Technology Appraisal program, the first treatment for hemophilia it has recommended, and the first pilot for the outcomes-based scheme as part of the commitments in the 2024 VPAG.

"Our final draft guidance recommending the treatment for around 260 adults with moderately severe or severe hemophilia B meant it also became the first medicine to go into the Innovative Medicines Fund," adds NICE.

NICE's document states that the price per treatment for a single dose of Hemgenix is £2,600,000. However, the company has a commercial arrangement that makes Hemgenix available to the NHS at a discounted price.

According to data from the Patient Access Schemes Liaison Unit (PASLU), simple discounts remain the most common approach, with over 70%, followed by commercial access agreements, with 16%.

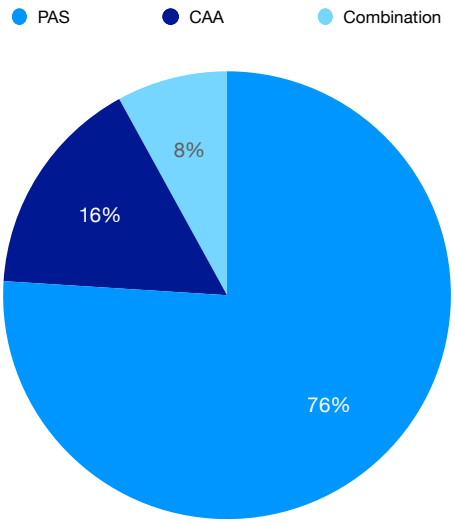
However, NHS England notes that unusual circumstances can surround the NICE technology appraisal of a particular treatment, making its launch challenging or commercially unviable.

Meanwhile, NICE also highlighted that its appraisal of Vertex's cystic fibrosis medicines is one of the first times non-cancer medicines have received additional weighting with the new severity modifier and is a key reason why NICE has been able to recommend them.

Vertex is now trying to secure similar agreements in Scotland, Wales and Northern Ireland. Meanwhile, the company is discussing with NHS England and NICE about its next-generation CF treatment, known as vanza triple, which is expected to file for global approval by mid-2024.

Scheme Type	Description
Budget cap	Max budget impact for product(s) beyond which central rebate is payable
Price/volume agreement	Price agreed for set volume of patients & then reductions staged based on additional patient numbers, or company pays back the full amount (similar to budget cap)
Cost sharing	The company funds initial cost of therapies such as offering the first month for free
Stop/start criteria	Rules on eligibility criteria for when patients would start/stop therapy
Outcomes-based agreement/ payment by results	Discount or rebate applied if a product does not perform as expected or for non-responders

Source: NHS - Types of commercial agreements



Germany Edges Closer to Confidential Pricing Option

Date: 08 Jul 2024 | #EUROPE #GERMANY #Medical Research Act #AMNOG #Bundestag #Confidential Pricing #Germany #MFG

NAVLIN BRIEF:

- Last week, the Health Committee (Bundestag) approved the Federal Government's Medical Research Act (MFG), with some amendments. The major point of contention—the proposal for confidential reimbursement amounts for new patent-protected drugs—was adjusted to clarify that only pharmaceutical companies with German research departments will qualify, drug makers have five days to choose between confidential or transparent pricing, and choosing confidentiality comes with a standardized 9% discount on the agreed price
- According to Alan Crowther, EVERSANA's General Manager of Global Pricing, Access, and Digital Solutions, there are key implications that immediately surface, and the move signifies that "Confidentiality as an option may be increasing somewhat in health systems around the world, but at a cost to manufacturers"
- Read on to understand more about the consequences of this major change in Germany

BERLIN, Germany – Last week, the Health Committee (Bundestag) approved the Federal Government's Medical Research Act (MFG), with some amendments.

The major point of contention—the proposal for confidential reimbursement amounts for new patent-protected drugs—was adjusted. The regulation will now be limited to the end of June 2028, with an evaluation set for late 2026.

According to a release, only pharmaceutical companies with drug research departments in Germany, and who can demonstrate "relevant own projects and cooperation with public institutions in preclinical or clinical drug research in Germany," will qualify for confidential pricing.

After concluding price negotiations, manufacturers will have five days to choose between secret or transparent reimbursement amounts. Opting for secret amounts will incur an additional 9% discount on the negotiated price.

The impending plenary session vote will determine the final outcome of the MFG. If the bill goes ahead as it is currently written, it will significantly impact the German pricing and reimbursement landscape.

According to Alan Crowther, EVERSANA's General Manager of Global Pricing, Access, and Digital Solutions, three key implications immediately surface:

- The requirements likely burdens small firms more heavily than large, similar to the European pharma legislation
- Pricing & market access need to be involved in decisions like trial design and resource allocation (for example, R&D, manufacturing) more and more, and P&MA teams need to advocate for a seat at the table
- Firms need to have appropriate scenario planning for negotiations

Additionally, he calls the 9% discount "interesting," in the sense that "Similar to France's indirect method (vs. this direct model), the Federal Ministry of Health legislation is saying "if you see value in confidential pricing, then we want a share in that value." Confidentiality as an option may be increasing somewhat in health systems around the world, but at a cost to manufacturers."

The Legal Contents

Under the MFG, the approval process for medicinal products and the authorization and conduct of clinical trials are streamlined. This includes improving cooperation between drug approval authorities, harmonizing ethics committees, and establishing standard contractual clauses. Processing time for clinical trials conducted solely in Germany is reduced to 26 days.

The draft law now includes provisions to promote academic studies, align pharmaceutical regulations with medical device laws, and recognize third-country inspections, particularly in China.

Negotiation flexibility for drug prices is being increased. Until June 30, 2028, pharmaceutical companies can agree on confidential reimbursement amounts for new drugs, resulting in a 9% price reduction if the company has a drug research department, relevant projects, and cooperation with public institutions in Germany. This regulation will be reviewed in 2026. Additionally, information on the cost-effectiveness of these drugs will be required in electronic prescription systems used by contract doctors.

Incentives for research include reinstating the negotiation framework for reimbursement amounts (essentially being freed from the "guardrails" from the GKV-Financial Stabilization Act) if at least 5% of approval study subjects participated in clinical trials in Germany. This applies for three years, unless the company demonstrates it has a drug research department and relevant projects and collaborations in Germany.

Bundestag Backs Amended Medical Research Act

Date: 05 Jul 2024 | #EUROPE #GERMANY #Confidential Drug Pricing #Medical Research Act #Bundestag #Germany #MFG

NAVLIN BRIEF:

- The Federal Government's Medical Research Act (MFG) in Germany has been approved by the Health Committee (Bundestag), after endorsing 26 amendments proposed by the coalition
- Interestingly, the contentious issue of confidential pricing for new patent-protected drugs has been revised and clarified: Only pharmaceutical companies with German research departments will qualify, drug makers have five days to choose between confidential or transparent pricing, and choosing confidentiality comes with a standardized 9% discount on the agreed price
- The final outcome of the MFG will depend on the upcoming plenary session vote

THE DETAILS

BERLIN, Germany – The Health Committee (Bundestag) has approved the Federal Government's Medical Research Act (MFG) with some amendments. On Wednesday, a majority of MPs endorsed 26 coalition-proposed amendments, while the opposition unanimously opposed the bill. The revised legislation is scheduled for a plenary vote on Thursday 4.

The major point of contention—the proposal for confidential reimbursement amounts for new patent-protected drugs—has been adjusted. The regulation will now be limited to the end of June 2028, with an evaluation set for late 2026.

According to a release, only pharmaceutical companies with drug research departments in Germany, and who can demonstrate "relevant own projects and cooperation with public institutions in preclinical or clinical drug research in Germany," will qualify for confidential pricing.

After concluding price negotiations, manufacturers will have five days to choose between secret or transparent reimbursement amounts. Opting for secret amounts will incur an additional 9% discount on the negotiated price.

The impending plenary session vote will determine the final outcome of the MFG.

France's HAS 2023 Activity Report: Increased ASMR Recognition & Relaxed Evidence Requirements for HTA

Date: 01 Jul 2024 | #EUROPE #FRANCE #COVID-19 #CT #Transparency Committee #Moderna #ASMR #SMR #HAS #Spikevax #Early Access

NAVLIN BRIEF:

- France's High Authority for Health (HAS) has published its 2023 activity report, revealing that the Transparency Committee (CT) delivered 462 opinions over the year. This includes 123 opinions in the context of early access and 220 related to requests for information on the inclusion of medications or extension of coverage
- The CT noted a significant rise in the recognition of ASMR ratings, particularly ASMR I to III, from 7 in 2015 to 18 in 2023. However, the percentage of ASMR I to IV ratings decreased from 21% in 2022 to 14% in 2023. Moderna's COVID-19 vaccine, Spikevax, was the only product to receive an ASMR II ("Important") rating in 2023
- The CT updated its doctrine to balance accelerated clinical development with uncertainty levels, accepting studies without comparator arms under specific conditions. These include a justified impossibility of comparative trials, predetermined external comparators, and rigorous matching

THE DETAILS

PARIS, France - The HAS has published its 2023 activity report, highlighting key insights from the CT, which evaluates the therapeutic value and makes reimbursement recommendations. In 2023, only one product, Moderna's COVID-19 vaccine Spikevax, received an actual therapeutic benefit rating of ASMR II ("Important"), and no product received an ASMR I ("Major") rating.

The report notes a significant increase in the recognition of ASMR ratings, particularly ASMR I to III, from 7 (6% of registrations/extensions processed in the full procedure) in 2015 to 18 (14% of registrations/extensions processed in the full procedure) in 2023. However, the percentage of ASMR I to IV ratings for registrations/extensions processed in the full procedure decreased from 21% in 2022 to 14% in 2023.

Of the products recognized with an ASMR II to III in 2023, 67% (12 out of 18) were made available to patients before their assessment under common law, via the early access system. In total, the CT delivered 462 opinions in 2023, an increase of 2.6% compared to 2022. This includes 123 opinions in the context of early access and 220 related to requests for information on the inclusion of medications or extension of coverage.

Overall, 67% of innovative medicines showing at least a moderate improvement in actual benefit (ASMR I to III) in 2023 were already accessible via early access. The median processing time for requests for registration, extension of indication, and early access was 85 days, in line with the evaluation times stipulated by the transparency directive.

The report also includes an update on the doctrine of the CT, proposing a new approach that aims to balance of uncertainty, ultimately benefiting patients. While randomized controlled trials remain the gold standard for patient safety, the Committee now allows for a reduced level of evidence required for reimbursement of health products under specific conditions, by valuing indirect comparisons based on their methodological quality.

Specifically, the results of a study without a comparator arm may now be accepted, subject to three essential conditions:

1. A duly justified impossibility of evaluating the new drug in a comparative trial.

2. The choice of an external comparator must be decided upstream during the drafting of the study protocol, and not adapted based on the results of the single-arm trial.

3. Rigorous matching.

Thus, indirect comparison data of good methodological quality or data from control groups are now acceptable, provided they are explained and justified upstream by the manufacturer. Under this new policy, the CT evaluated a drug based on data from an indirect comparison and awarded an ASMR of IV.

Additionally, when recommending reimbursement for a new treatment, the Committee will continue to demand rigorous methodology to ensure its opinions are always scientifically valid, indicating when the data are insufficient to provide complete insight. The new doctrine recognizes that ASMR V can correspond to several types of situations, particularly those where the absence of added value is proven and those where a development plan with a given timetable could remove uncertainty.

Stakeholders Demand Revisions to EU Joint Clinical Assessment for ATMPs

Date: 11 Jul 2024 | #EUROPE #BELGIUM #RWE #JCA #ARM

NAVLIN BRIEF:

- The Alliance for Regenerative Medicine (ARM) warns that without methodologies suited for Advanced Therapy Medicinal Products (ATMPs), the implementation of the EU Joint Clinical Assessment (JCA) will create a new barrier to patient access
- Juan Ventura, Research & Patient Engagement Director, Cancer Patients Europe said: “Increasing patient access has been a key driver for the current mandate of the European Commission. It would be extremely counterproductive if the JCA, with all its honorable intentions, becomes an obstacle for patients to access life-saving therapies. While a promising JCA would give faster access to medicines and reduce inequality of access across Europe for cancer patients, the current JCA methodologies for assessing clinical benefit to patients do not take into account the unique nature of ATMPs”
- Overall, the group calls on the EU HTA Coordination Group to revise the JCA methodological guidance to avoid discrediting evidence from single-arm trials, and take a more pragmatic approach to running JCAs of ATMPs by using real-world data to fill evidence gaps

THE DETAILS

BRUSSELS, Belgium — Stakeholders have released a call to action urging the members of the HTA Coordination Group and its relevant subgroups and JCA assessors to recognize all types of available evidence, including single-arm trials and RWE, and to use the JCA report to describe, "rather than judge, any resulting uncertainty as to the treatments' benefits, as called for by the HTA Regulation."

The signatories of the call to action point out that the current JCA methodology considers datasets from single-arm or non-randomized trials as potentially insufficient, a stance that could be detrimental to ATMPs. These therapies, often developed for rare and ultra-rare diseases, typically rely on smaller, non-RCT datasets due to practical and ethical constraints.

"Insisting on RCTs for ATMPs is not only often unfeasible but also unethical in many cases," the statement asserts. "This could delay or deny access to life-saving treatments for patients with no other options."

The group advocates for a JCA process that recognizes all available evidence, including single-arm trials and real-world evidence (RWE). They argue that the HTA Regulation was designed to accommodate the unique data limitations of ATMPs, allowing Member States to handle the uncertainty of treatment benefits during the appraisal phase.

"The HTA Coordination Group must lead the development of a JCA system that meets healthcare needs without obstructing access to transformative therapies," the stakeholders urge. "Describing uncertainty, rather than dismissing evidence, is crucial for ensuring patient access to innovative treatments."

According to the group, ATMPs, including cell-based therapies like CAR-T for aggressive cancers and gene therapies for severe genetic disorders, offer hope to patients facing debilitating and life-threatening conditions. Examples like Kymriah, Zolgensma, and Libmeldy have shown significant success based on single-arm trials, underscoring the need for flexible and accommodating assessment methodologies.

Regulatory Misalignment

The group highlights a misalignment between the JCA guidelines and the EU HTA Regulation. While the regulation calls for the consideration of non-RCT evidence and limits JCA to describing uncertainty, the guidelines empower assessors to judge evidence sufficiency, potentially overstepping the regulation's intent.

Overall, the stakeholders demand that the JCA process be revised to better align with the HTA Regulation, ensuring it is fit-for-purpose for ATMPs. They call for the integration of scientifically robust methods that can accommodate the unique nature of ATMP clinical evidence, including the use of patient registries, observational studies, and historical control data.

EU Pharma Package: What do Member States Currently Think?

Date: 04 Jul 2024 | #EUROPE #BELGIUM #Belgium #Hungary #Pharmaceutical legislation #market exclusivity #European Commission #regulatory data protection

NAVLIN BRIEF:

- Hungary, which will hold the EU presidency from July to December 2024, will play a crucial role in implementing the European pharmaceutical legislation review and the joint EU health technology assessment (HTA) initiative. Technical discussions about the legislation resume on 3 and 4 July under the Hungarian Presidency, although some MEPs are worried about Hungary's credibility in fulfilling its role given its “lack of compliance with EU law and values and the principle of sincere cooperation"
- The changes, aimed for initiation in 2024, intend to reduce the protection duration from eight to six years. While countries such as Denmark, Italy, and Sweden criticized the unpredictability this creates, Spain and Portugal support a shorter duration of seven years
- The European Commission also suggests a hybrid approach to ensure pharmaceutical companies supply the European market. The Parliament favors incentives without mandatory supply requirements, with countries like Austria supporting this model. However, Latvia supports the Commission's original proposal, arguing it considers the unique aspects of national healthcare systems, while others like Estonia and the Czech Republic express skepticism or call for a more company-led initiative

THE DETAILS

BRUSSELS, Belgium – As technical discussions about the revision of pharmaceutical legislation resume on 3 and 4 July under the Hungarian Presidency, what is the position of the Member States on Articles 81 (regulatory data protection period) and 82 (the amended blanket launch incentives) of the Pharmaceutical Package Directive?

Hungary Inheriting the Legislation

The previous Presidency held by Belgium, which ended at the end of June, made significant progress with the European Health Union framework. However, key issues remain unresolved, particularly related to pharmaceutical legislation.

The legislation is not expected to be negotiated until 2026 and will likely not be in effect until 2028. The main concern for policymakers now is aligning these changes with the goal of enhancing Europe's competitiveness and resilience.

Hungary, which will hold the EU presidency from July to December 2024, will play a crucial role in implementing the European pharmaceutical legislation review and the joint EU health technology assessment (HTA) initiative. However, some MEPs are worried about Hungary's credibility in fulfilling its role given its “lack of compliance with EU law and values and the principle of sincere cooperation.”

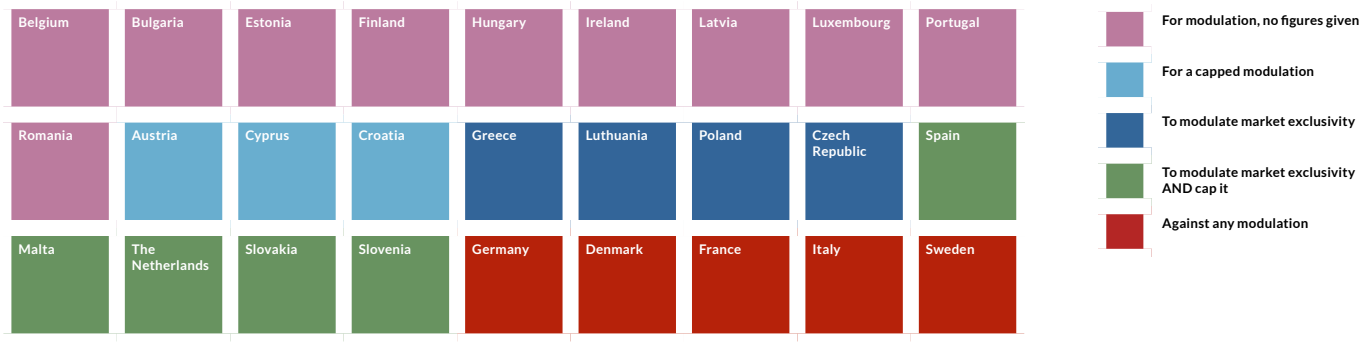
Article 81 of the Proposed Directive

The current regulatory framework, known as "8+2+1," provides a duration of protection for regulatory data at eight years, followed by two years of market exclusivity, with an additional year for new therapeutic indications. However, the European Commission's new proposal seeks to change this model by reducing the protection duration to six years and introducing a modulation system to potentially gain additional years under specific conditions.

The Belgian Presidency has suggested a ceiling on these modulations to ensure that the total duration does not exceed the current eleven years, proposing to modulate market exclusivity rather than the protection of regulatory data. While the majority of member states accept the principle of a modulated incentive system, a significant minority remains opposed. Denmark, Italy, and Sweden issued a joint statement following the European Health Ministers Council (Epsco) on June 21, criticizing the proposal. They argue that reducing the data protection period and replacing it with a complex set of incentives makes investment and market potential for innovative medicines more unpredictable and uncertain. They contend that this approach contradicts the EU's strategic goals of reducing bureaucracy to enhance competitiveness and achieve strategic autonomy.

From Croatia’s perspective, an acceptable incentive modulation system should ensure that all incentives, including transferable exclusivity vouchers, do not exceed the current eleven-year regulatory data protection period. The Belgian Presidency, excluding these vouchers from its cluster of articles on incentives, asked Member States to decide on an eleven-year cap and to discuss whether this period should include transferable exclusivity vouchers at a later stage.

During the Epsco Council, the Polish minister raised concerns about the eleven-year cap, questioning if it might delay the entry of generic drugs into the market. Only two states – Spain and Portugal – have spoken out in favor of seven years of regulatory data protection, in order to come closer to the European Parliament's proposed seven and a half.



Incentives vs. Obligations

The European Commission proposes a hybrid approach to ensure pharmaceutical companies supply the European market, suggesting an additional two years of regulatory data protection for those that do so within two years of marketing authorization (three years for SMEs). This blend of encouragement and obligation aims to address market needs effectively.

However, the European Parliament favors a more flexible solution, advocating incentives without mandatory supply requirements. Austria has voiced strong support for the incentive-based model but remains open to exploring an obligation-focused strategy.

Estonia, represented by Health Minister Riina Sikkut, expressed skepticism about the efficacy of public service obligations, stating, "the public service obligation already exists today and does not really work. We should not bet on something that we have proof does not work."

Latvia is the only country backing the European Commission's original proposal. It argues that the current alternatives fail to consider the unique aspects of national healthcare systems.

The Czech Republic, however, is hesitant to endorse any current option. Its Health Minister argues for a company-led initiative where firms first inform Member States about the requirements for specific pharmaceutical products. Member States would then decide on the product's relevance within their national context. Additionally, the Czech Republic supports separating market access from incentives.

All originally researched and reported by Contexte.

Connecticut Court Dismisses Boehringer Ingelheim's IRA Lawsuit

Date: 09 Jul 2024 | #JARDIANCE #DIABETOLOGY #BOEHRINGER INGELHEIM #NORTH AMERICA #UNITED STATES #ruling #decision #litigation #lawsuit #IRA #Medicare Drug Price Negotiation Program

NAVLIN BRIEF:

- A Connecticut judge dismissed Boehringer Ingelheim's lawsuit against the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program in another legal blow to the pharmaceutical industry last week
- BMS originally filed a lawsuit against the IRA in August of 2023, arguing that the program is an involuntary scheme that violates several constitutional rights, including the First, Fifth, and Eight Amendments. However, Chief District Judge Michael Shea dismissed each of the drugmaker's claims, finding that the drugmaker's participation in Medicare is voluntary
- The courts have also dismissed lawsuits against the IRA from Bristol Myers Squibb, Johnson & Johnson, AstraZeneca, the U.S. Chamber of Commerce, and the Pharmaceutical Research and Manufacturers of America (PhRMA)

THE DETAILS

HARTFORD, CT, United States – A Connecticut judge handed Boehringer Ingelheim a loss in its lawsuit against the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program, dismissing the manufacturer's claims that the program is unconstitutional.

BMS originally filed a lawsuit against the IRA in August of 2023, arguing that the program is an involuntary scheme that violates several constitutional rights, including the Fifth Amendment right to due process and just compensation; the Eighth Amendment's excessive fines clause, and the First Amendment's protection of free speech by forcing manufacturers to "agree" with the prices set by the U.S. government. However, Chief District Judge Michael Shea dismissed each of the drugmaker's claims.

Specifically, Judge Shea ruled that because a drugmaker's participation in Medicare is voluntary, the IRA does not violate the Fifth Amendment or "compel" a manufacturer to do or say anything in a way that violates the First Amendment.

In the 47-page decision, Judge Shea wrote, "I see no reason that voluntary participation in a government program should amount to a deprivation of property any more than it amounts to a taking of property."

"The federal government is free to use its economic power as a bulk purchaser of certain goods to negotiate better deals for those goods," Shea added.

The ruling is the latest in a series of losses for the pharmaceutical industry, which has been attempting to block the controversial drug pricing program from going into place since the law was enacted in August 2022.

In May, a federal judge for the District of New Jersey ruled against Bristol Myers Squibb (BMS) and Johnson & Johnson (J&J), similarly concluding that the negotiation program "does not result in a physical taking nor direct appropriation" because participation in Medicare is completely voluntary.

In early March, a federal judge in Delaware rejected AstraZeneca's similar lawsuit, finding that the company's arguments against the Administrative Procedure Act (APA) have no standing and that because participation in Medicare is voluntary, AstraZeneca's due process claim "fails as a matter of law."

In October 2023, an Ohio federal judge declined to grant a preliminary injunction requested by the U.S. Chamber of Commerce to pause the negotiation program while lawsuits against the program proceed.

Additionally, in February, a federal court in Texas dismissed a lawsuit filed by the Pharmaceutical Research and Manufacturers of America (PhRMA) and two other organizations against the IRA, finding that one of the plaintiffs—the National Infusion Center Association (NICA)—does not have standing because it does not manufacture or sell prescription medications that could be subject to negotiation. Because NICA is the only plaintiff based in Texas, Judge David Ezra found that the lawsuit is now in an improper venue and should be dismissed.

Meanwhile, negotiations for the first ten prescription drugs selected under the controversial program are currently underway and the Centers for Medicare & Medicaid Services (CMS) is expected to publish any agreed-upon negotiated prices for the selected drugs by September 1, 2024.

FTC Finds PBMs Hold "Significant Power" Over Americans' Access to Prescription Drugs

Date: 10 Jul 2024 | #NORTH AMERICA #UNITED STATES #antitrust #access #FTC #report #investigation #competition #consolidation #PBMs #pricing #affordability

NAVLIN BRIEF:

- The Federal Trade Commission (FTC) published a report examining the state of the pharmacy benefit manager (PBM) industry and its influence on prescription drug access in the U.S., finding that consolidation and vertical integration within the industry have "allowed PBMs to profit at the expense of patients and independent pharmacists"
- The interim report comes two years after the antitrust watchdog launched a formal inquiry into PBM practices. At the time, the FTC issued orders requesting information from the six largest PBMs: CVS Caremark; Express Scripts, Inc.; OptumRx, Inc.; Humana Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc. The FTC also issued orders to Zinc Health Services, LLC; Ascent Health Services, LLC; and Emisar Pharma Services LLC, which are group purchasing organizations that negotiate drug rebates on behalf of PBMs
- Commissioner Melissa Holyoak did not agree with the results of the report and voted against its publication. According to Holyoak, the FTC report is "premature" and does not provide a better understanding of the competition concerns surrounding PBMs or how consumers are impacted by PBM practices

THE DETAILS

WASHINGTON, DC, United States – The Federal Trade Commission (FTC) published its long-awaited report examining the state of the pharmacy benefit manager (PBM) industry and its influence on prescription drug access in the U.S.

The interim report comes two years after the antitrust watchdog launched a formal inquiry into PBM practices. At the time, the FTC issued orders under Section 6(b) of the FTC Act requesting information from the six largest PBMs: CVS Caremark; Express Scripts, Inc.; OptumRx, Inc.; Humana Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.

In 2023, the FTC issued additional orders to Zinc Health Services, LLC; Ascent Health Services, LLC; and Emisar Pharma Services LLC, which are group purchasing organizations that negotiate drug rebates on behalf of PBMs.

Overall, the report provides insight into the ways PBMs may be impacting access to and affordability of prescription medicines. According to the FTC, the six largest PBMs manage over 90% of all prescriptions filled in the U.S., while the three largest PBMs now manage nearly 80%. This consolidation and the trend toward vertical integration among PBMs grants the middlemen outsized influence on the prescription drug market, according to the FTC.

Using the documents gathered in their investigation and additional, publicly available information, the agency found that:

- The market for pharmacy benefit management services has become highly concentrated, and the largest PBMs are now also vertically integrated with the nation's largest health insurers and specialty and retail pharmacies
- As a result of this high degree of consolidation and vertical integration, the leading PBMs can now exercise significant power over Americans' access to drugs and the prices they pay
- Vertically integrated PBMs may have the ability and incentive to prefer their own affiliated businesses, which in turn can disadvantage unaffiliated pharmacies and increase prescription drug costs
- Evidence suggests that increased concentration may give the leading PBMs the leverage to enter into complex and opaque contractual relationships that may disadvantage smaller, unaffiliated pharmacies and the patients they serve
- PBMs and brand drug manufacturers sometimes negotiate prescription drug rebates that are expressly conditioned on limiting access to potentially lower cost generic alternatives

Overall, the FTC concludes that these dynamics have "allowed PBMs to profit at the expense of patients and independent pharmacists."

FTC Chair Lina Khan commented, "The FTC's interim report lays out how dominant pharmacy benefit managers can hike the cost of drugs—including overcharging patients for cancer drugs. The report also details how PBMs can squeeze independent pharmacies that many Americans—especially those in rural communities—depend on for essential care."

"The FTC will continue to use all our tools and authorities to scrutinize dominant players across healthcare markets and ensure that Americans can access affordable healthcare," Khan added.

However, the report falls short of calling for any antitrust action against the pharmaceutical middlemen.

Notably, one of the five FTC commissioners voted against issuing the interim report and published a dissenting statement. Commissioner Melissa Holyoak argues that the FTC report is "premature," fails to meet the "rigorous standard" of prior reports, and was "plagued by process irregularities and concerns over the substance…of the original order."

Additionally, Commissioner Holyoak found that the report does not provide a better understanding of the competition concerns surrounding PBMs or how consumers are impacted by PBM practices.

One concern is that several of the PBMs that received orders did not complete their required submissions, which impacts the completeness of the report. The FTC notes that it could pursue legal routes to compel PBM compliance and "remains committed to providing timely updates as the Commission receives and reviews additional information."

Background

PBMs, which are companies that manage prescription drug benefits on behalf of payers (e.g., insurers, Medicare Part D drug plans, large employers), negotiate with drug manufacturers and pharmacies to control drug spending. However, the processes and calculations PBMs use are often complex and opaque, leading to large inconsistencies and variability throughout the pharmaceutical pricing chain. The middlemen have also been accused of pursuing profit-boosting tactics that drive up the cost of prescription drugs.

Over the past few years, the lack of transparency and growing influence of PBMs have gained the public's attention and inspired scrutiny from lawmakers and regulators alike.

Lawmakers have introduced and advanced a number of policies intended to address these concerns, including measures to "de-link" PBM fees from the price of drugs, improve transparency, and prohibit practices like spread pricing and patient steering.

However, while reforming PBMs has garnered broad bipartisan interest and support, Congress has yet to advance one of the multiple PBM bills introduced by lawmakers.

FTC Prepares to Sue Top Three PBMs Over Insulin Prices

Date: 12 Jul 2024 | #INSULIN #DIABETES MELLITUS #DIABETOLOGY #NORTH AMERICA #UNITED STATES #CVS #FTC #litigation #Cigna #lawsuit #rebate #PBM #UnitedHealth #pricing

NAVLIN BRIEF:

- The U.S. Federal Trade Commission (FTC) is planning to file lawsuits against the three largest pharmacy benefit managers (PBMs) in the U.S. over their role in driving up the cost of insulin
- According to reporting from the WSJ, the FTC intends to target rebate schemes negotiated with drug manufacturers regarding insulin products. The FTC is also expected to investigate the role that insulin manufacturers play in these negotiations
- This is not the first time PBMs have faced scrutiny over their role in insulin prices. Several states have already taken their own steps to hold the pharmaceutical middlemen accountable for driving up the cost of insulin, including Michigan, California, Arizona, Virginia, Arkansas, and Ohio

THE DETAILS

WASHINGTON, DC, United States – The U.S. Federal Trade Commission (FTC) is planning to file lawsuits against the three largest pharmacy benefit managers (PBMs) in the U.S. over their role in driving up the cost of insulin, according to reporting from the Wall Street Journal (WSJ).

Specifically, the FTC will sue UnitedHealth, Cigna, and CVS Health, which together control nearly 80% of the PBM market. The WSJ notes that the lawsuits will target rebate schemes negotiated with drug manufacturers regarding insulin products. The FTC is also expected to investigate the role that insulin manufacturers play in these negotiations.

The news comes just days after the FTC published an interim report examining the state of the pharmacy benefit manager (PBM) industry and its influence on prescription drug access in the U.S. The report, which is the first result of a two-year investigation into PBM practices, found that consolidation and vertical integration within the industry have "allowed PBMs to profit at the expense of patients and independent pharmacists" and confirmed that PBMs use their size and influence to drive up costs and disadvantage smaller, independent pharmacies.

However, this is not the first time PBMs have faced scrutiny over their role in insulin prices. Several states have already taken their own steps to hold the pharmaceutical middlemen accountable for driving up the cost of this lifesaving medicine.

Most recently, the Michigan counties of Wayne, Washtenaw, Macomb, and Monroe filed lawsuits against the top three insulin manufacturers and largest PBMs, accusing the defendants of illegal price-fixing for insulin products.

The counties are accusing the defendants of violating the Racketeer Influenced and Corrupt Organizations Act, the Sherman Anti-Trust Act, the Michigan Anti-Trust Act and the Consumer Protection Act and are suing to recover damages associated with the costs that county employees, retirees and their dependents, and other county programs have paid for insulin over the last 20 years.

Several states have filed similar lawsuits over the past couple of years, including California, Arizona, Virginia, Arkansas, and Ohio, among others.

Insulin prices have been the subject of policymaker scrutiny for several years now. In response to public backlash and lawmaker pressure, the major insulin manufacturers—Eli Lilly, Novo Nordisk, and Sanofi—announced they would make significant price cuts to certain insulin products.

However, many of the recent lawsuits are seeking to recoup alleged overpayments due to years of inflated prices.

Most of these lawsuits implicate PBMs in addition to the manufacturers themselves. According to the litigation, the rebate system utilized by PBMs encourages the formulary preference of more expensive products and incentivizes manufacturers to inflate insulin list prices. These prices are then ultimately passed on to consumers and health plans.

85% of Patients Discontinue GLP-1 Medicines for Weight Loss After Two Years, PBM Study Finds

Date: 12 Jul 2024 | #OBESITY #WEIGHT LOSS #DIABETOLOGY #NORTH AMERICA #UNITED STATES #coverage #study #GLP-1 #Magellan Rx #adherence #persistence #Prime Therapeutics #analysis #value

NAVLIN BRIEF:

- A new analysis conducted by Prime Therapeutics/Megellan Rx Management (Prime/MRx) has found that the vast majority of patients using GLP-1 agonist drugs for weight loss stop treatment within two years
- Specifically, among a sample of 3,364 commercially insured members who were prescribed GLP-1s for weight loss and who did not have a diagnosis of diabetes, Prime/MRx found that 85% of individuals who newly started GLP-1 agonist drugs for weight loss were no longer taking the drug after two years, and 71% of individuals were no longer taking these drugs for weight loss at one year
- The study reinforces payer fears regarding the value of covering these weight-loss drugs, especially considering their high cost and the fact that many patients regain the weight lost through GLP-1 therapy after they cease treatment

THE DETAILS

EAGAN, MN, United States – Pharmacy Benefit Manager (PBM) Prime Therapeutics/Magellan Rx Management (Prime/MRx) published an analysis suggesting that most patients who start taking GLP-1 agonist drugs for weight loss discontinue treatment within two years.

To conduct the study, Prime/MRx analyzed integrated pharmacy and medical claims data from 16 million commercially insured members. After selecting for patients taking GLP-1 drugs for obesity (and without diabetes) during the study period, a total of 3,364 commercially insured members were included in the analysis.

Prime/MRx then analyzed the data to determine two-year GLP-1 obesity treatment adherence and persistency among these members. Overall, Prime/MRx found that:

- 85% of individuals who newly started GLP-1 agonist drugs for weight loss were no longer taking the drug after two years
- 71% of individuals were no longer taking these drugs for weight loss at one year
- Although persistence among the 45% of the population using weekly-dosed semaglutide (Ozempic and Wegovy) was better, still only 1 in 4 of these patients remained on GLP-1 therapy at two years
- At two years, 26% of individuals switched GLP-1 drugs during therapy—an increase from 11% at one year

Regarding the results, David Lassen, PharmD, Chief Clinical Officer at Prime/MRx, commented, "GLP-1s are unlikely to deliver therapeutic value when so many individuals stop treatment after two years, but the findings also illustrate the need for obesity care management programs to improve adherence."

"A significant number of individuals in this study switched GLP-1 drugs, and we will continue to assess the cause and monitor the impact of switching products over time. Prime/MRx is committed to using our real-world research to help our clients make informed benefit decisions for GLP-1 coverage as they navigate this dynamic landscape," added Lassen.

Although evidence of the medical benefit of these medicines continues to grow stronger, insurers are hesitating to cover GLP-1s for weight loss as concerns around cost and adherence surge. Low medication adherence and early discontinuation of GLP-1s for weight loss is compounded by the fact that for many patients, weight lost while taking a GLP-1 receptor agonist is quickly regained after ceasing treatment. Considering these trends, as well as the high cost of GLP-1s, many payers are concerned that covering these drugs for weight loss may return little therapeutic value and contribute significantly to drug spending waste.

Citing these concerns, some payers have even begun to restrict coverage. At the beginning of June, Blue Cross Blue Shield (BCBS) of Michigan announced that it will stop covering weight-loss drugs for its fully insured large group commercial members beginning January 1, 2025.

According to BCBS, the decision to end coverage of GLP-1 receptor agonists for weight-loss is backed by research demonstrating that most patients are not staying on these medications long enough to see a benefit. The insurer stated, "Due to the high cost of these drugs and supply considerations, we want to ensure they are used for the most appropriate patients who can achieve clinical benefit. Additional research is needed to understand whether GLP-1 interventions lead to lower medical costs in the long term."

BCBS Michigan is not the only insurer to drop or restrict coverage of weight-loss drugs over the past several months. Other payers that have decided to forego coverage altogether include the University of Texas

system, which dropped coverage of weight loss drugs in September, citing the "excessive cost" manufacturers charge for these medications.

Minnesota-based Hennepin Healthcare and St. Louis-based Ascension also dropped coverage for weight loss drugs from their employee plans in the fall.

In February, the North Carolina State Health Plan Board of Trustees also voted to discontinue coverage of GLP-1 receptor agonists for the treatment of weight-loss beginning April 1, 2024. At the time, the Board said it would revisit coverage of obesity drugs if Novo Nordisk and CVS/Caremark are willing to cut the price.

U.S. Market Share of Humira Drops Amid Rise in Biosimilar Competition

Date: 16 Jul 2024 | #AMJEVITA #HADLIMA #ADALIMUMAB #HYRIMOZ #HUMIRA #ABRILADA #YUSIMRY #CYLTEZO #HULIO #SIMLANDI #IDACIO #YUFLYMA #NORTH AMERICA #UNITED STATES #biosimilars #Humira #market share #WAC #AbbVie #adalimumab

NAVLIN BRIEF:

- Humira's market share fell from 96% to 82% between March and May 2024, according to Samsung Bioepis' Q3 2024 Biosimilar Market Report
- Following CVS' decision to eliminate branded Humira from some of its formularies in April, sales of biosimilars, especially Cordavis-labeled Hyrimoz, have skyrocketed. The report also mentions aggressive pricing strategies from Hadlima and Yusimry, offering costs up to 86% lower than Humira
- Additionally, it shows that biosimilar brands are adopting various pricing models to compete effectively. Some brands, like Cyltezo, Amjevita, Hulio, Idacio, Yuflyma, Abrilada, and Simlandi, provide dual or multiple WAC options to cater to different segments of the market. Amjevita, for example, is available only at a lower WAC for its high concentration form

THE DETAILS

WASHINGTON D.C., United States – According to Samsung Bioepis' Q3 2024 Biosimilar Market Report, Humira's (adulimumab) market share has decreased to 82% as of May 2024, a drop of 13% since March 2024.The once dominant product in immunology treatments is witnessing a significant decline in market share as biosimilars penetrate deeper into the market.

Humira is a monoclonal antibody therapeutic that works by targeting TNF-alpha, a pro-inflammatory cytokine that has been established as a key player in several immune-mediated conditions. The FDA first granted Humira approval in 2002 for rheumatoid arthritis, but the biologic has since become one of AbbVie's most valuable assets winning additional indications for Crohn's disease and ulcerative colitis.

After over 20 years of market dominance, AbbVie's blockbuster drug faced a wave of biosimilar competition in the U.S. last summer following the expiration of several patents protecting the drug. Humira biosimilars first entered the U.S. market in January 2023, led by Amgen's Amjevita.

According to Kaiser Family Foundation (KFF), the competition from adalimumab biosimilars could save the U.S. health care system approximately $9 billion. In July, Cigna's health services business estimated that these biosimilars could save the U.S. $225 billion to $375 billion in total pharmacy spend over the next decade.

U.S. sales of adalimumab biosimilars skyrocketed in April following a decision from CVS' pharmacy benefit manager (PBM) to remove the branded reference product, AbbVie's Humira, from some of its formularies.

The report highlights Cordavis-labeled Hyrimoz as the primary biosimilar eroding Humira's market presence, holding a 10% share by itself and contributing to Cordavis products' overall 28% share in the Humira market. Other notable biosimilars include Hadlima and Yusimry, which have introduced aggressive pricing strategies, offering Wholesale Acquisition Costs (WAC) 85-86% lower than Humira's.

Additionally, it shows that biosimilar brands are adopting various pricing models to compete effectively. Some brands, like Cyltezo, Amjevita, Hulio, Idacio, Yuflyma, Abrilada, and Simlandi, provide dual or multiple WAC options to cater to different segments of the market. Amjevita, for example, is available only at a lower WAC for its high concentration form.

Scripius, a PBM subsidiary of Intermountain Healthcare, exemplifies the proactive shift towards biosimilars. Beginning in early 2023, Scripius initiated the removal of Humira from its Medicaid formulary, later extending this to Medicare and commercial plans. Their aggressive strategy has led to a 98% transition of Humira prescriptions to biosimilars, marking one of the swiftest adoptions in the industry.

British Columbia Receives Funding to Improve Access to Rare Disease Medications

Date: 25 Jul 2024 | #OXLUMO #POTELIGEO #ONCOLOGY #METABOLIC DEFICIENCY #KYOWA KIRIN #ALNYLAM #NORTH AMERICA #CANADA-BRITISH COLUMBIA #coverage #CORD #funding #access #agreement #award #rare disease #Health Canada #common list

NAVLIN BRIEF:

- British Columbia has signed an agreement with Health Canada to invest a total of $194 million over three years to improve access to new drugs for rare diseases for its residents and to support enhanced access to existing drugs, early diagnosis, and screening for rare diseases
- The award comes from a tranche of $1.4 billion in funding that Health Canada announced last March as part of Canada's National Strategy for Drugs for Rare Diseases
- The first two drugs that will be covered include Kyowa Kirin's Poteligeo (mogamulizumab-kpkc), for the treatment of mycosis fungoides or Sézary syndrome, and Alnylam's Oxlumo (lumasiran), for the treatment of primary hyperoxaluria type 1

THE DETAILS

VICTORIA, British Columbia – British Columbia has signed an agreement with Health Canada to invest a total of $194 million over three years to improve access to new drugs for rare diseases for its residents and to support enhanced access to existing drugs, early diagnosis, and screening for rare diseases.

The award comes from a tranche of $1.4 billion in funding that Health Canada announced last March as part of Canada's *National Strategy for Drugs for Rare Diseases*. Over the past year, Health Canada has been engaging with provinces and territories to determine a small "common list" of new and emerging drugs to be funded and cost-shared across the country.

The first two drugs on the common list to be announced include Kyowa Kirin's Poteligeo (mogamulizumab-kpkc), for the treatment of mycosis fungoides or Sézary syndrome, and Alnylam's Oxlumo (lumasiran), for the treatment of primary hyperoxaluria type 1.

Health Canada will publish the names of drugs on the common list as the pan-Canadian Pharmaceutical Alliance concludes its price negotiations. The agency will also add information on which drugs each province and territory has elected to make available to their residents under bilateral agreements.

By signing the bilateral agreement, British Columbia is confirming that it is electing to make these two drugs available to its residents. According to Health Canada, Poteligeo will be subject to eligibility and rules of British Columbia Cancer drug funding. Funding of Oxlumo will be subject to patient eligibility and the rules of the Expensive Drugs for Rare Diseases process in British Columbia.

The agreement also commits British Columbia to work with Canada and other provinces and territories that may sign bilateral agreements on developing and implementing a plan for improving screening and diagnostics for rare diseases.

Health Canada notes that this planning work will take place over the first two years of the agreement period, with investments to begin no later than the third year.

Additional information on the *National Strategy for Drugs for Rare Diseases* is available here.

The recent announcement has been met with a lukewarm response from Canadian rare disease advocacy group, the Canadian Organization for Rare Disorders (CORD). Following the news of the bilateral agreement, CORD released a statement applauding the step, but expressing disappointment regarding the initial common list.

CORD wrote that the organization "Remains very disappointed that we remain in the dark regarding the other ten medicines that have been pre-negotiated as eligible for access to the new funding. We had no input on which medicines would qualify for the enhanced federal funding."

Additionally, CORD notes that the organization does not know what the announcement means for their patient organization members, which "may be called upon to help generate and contribute to the real world evidence required."

As a result, CORD plans to hold a webinar for members to discuss the new bilateral agreement and to advance any outstanding questions.

BIOSECURE Act Approaches Full House Vote in Fall

Date: 12 Jul 2024 | #ASIA & SOUTH PACIFIC #NORTH AMERICA #UNITED STATES #CHINA #BGI #Beijing Genomics Institute #Complete Genomics #WuXi AppTec #BIOSECURE #house #MGI

NAVLIN BRIEF:

- The BIOSECURE Act is advancing toward a full House vote this fall, according to House Speaker Mike Johnson
- The Act aims to end U.S. federal contracts and partnerships with China-based biotech companies, meaning that the Chinese contractors would no longer have slots on Medicaid and Medicare
- The advancement follows last month's setback when the Act was left out of a priority list of amendments

THE DETAILS

WASHINGTON, D.C., United States — The BIOSECURE Act is advancing toward a full House vote this fall, announced House Speaker Mike Johnson (R-La).

Johnson said at the conservative think tank, the Hudson Institute, "We will vote on the BIOSECURE Act."

Last month, the Act was left off a priority list of amendments. The House Rules Committee had stopped short of including the legislation among the finalists to be considered for inclusion in the National Defense Authorization Act (NDAA) for Fiscal Year 2025, reported BioSpace. The NDAA is a bicameral deal delineating the U.S. Department of Defense budget.

Regardless, BioCentury had reported that the Act was still scheduled to be implemented this year.

Introduced in January, the BIOSECURE Act aims to end U.S. federal contracts and partnerships with China-based biotech companies, including WuXi AppTec, Complete Genomics, Beijing Genomics Institute (BGI), and MGI. The break-off would mean Chinese contractors no longer have slots on Medicaid and Medicare.

In May, the Act was revised to give existing contracts until the beginning of 2032 before losing their validity.

WuXi AppTec was pressured to leave trade group Biotechnology Industry Organization (BIO). BIO's CEO John Crowley supports the Act's decoupling deadline, calling it a "reasonable timeframe."

Johnson's push to vote on the Act was celebrated by the Select Committee on the CCP Rep. John Moolenaar (R-Mich.). He said, "for the remainder of this Congress and into the next, the Select Committee will work in a bipartisan manner and alongside the committees of jurisdiction to continue to protect the United States and our values from the malign influence of our nation's foremost adversary, the Chinese Communist Party."

WuXi plays a significant role in the U.S. pharmaceutical market, found the New York Times. It makes ingredients for blockbuster therapies for leukemia, lymphoma, obesity, and HIV.

Many global companies have defied the unease churned by the U.S. bill by celebrating growing revenue and new product launches in China, but they are sometimes mitigating risk through diversified business deals.

A large swath of the industry is already taking action ahead of the Act's advancement, according to a new survey. The international survey, conducted last month by LEK Consulting, includes feedback from investors, biopharma companies, and CROs/CDMOs. The survey found that 68% of companies are revising related activities such as legal and compliance criteria, background checks for partners, and supplier diversification.

Novo Nordisk's Weight-loss Shot, Wegovy, Approved in China

Date: 01 Jul 2024 | #OZEMPIC #WEGOVY #OBESITY #DIABETOLOGY #NOVO NORDISK #ASIA & SOUTH PACIFIC #CHINA #GLP-1 #NMPA #Catalent #semaglutide

NAVLIN BRIEF:

- Novo Nordisk's weekly injection, Wegovy (semaglutide), received approval in China for long-term weight management
- Wegovy is a higher dosage of the same active ingredient as Ozempic which is only approved in China for Type 2 diabetes patients, though sales have surged on the gray market
- Novo Nordisk's semaglutide patent will expire in China in 2026, but a legal battle could strike down the patent sooner, paving the way for Chinese generics

THE DETAILS

BEIJING, China — Novo Nordisk's weekly injection, Wegovy (semaglutide), received approval in China for long-term weight management.

Wegovy is a higher dosage of the same active ingredient as Ozempic which is only approved in China for Type 2 diabetes patients. Ozempic's sales have surged on China's gray market as GLP-1s gain traction as an effective method of weight-loss.

First approved in 2021, Ozempic sales in Greater China doubled last year, reaching $700 million. China represents the world's largest obese population, with 200 million obese adults and another 400 million people considered overweight, according to official data.

Due to supply limits, Novo Nordisk is planning a restrained launch of Wegovy with the help of CDMO Catalent. Novo acquired Catalent in a $16.5 billion deal after struggling to meet world demand for Wegovy.

Pricing and details on availability for Wegovy will be released once the drug is launched in China, reported Reuters. The company said it would first target patients in China who pay out-of-pocket.

Rose Niu Wei, a marketing manager at one of Beijing's major medical institutions, Raffles Hospital Beijing, told Reuters the hospital ordered Wegovy around last September, but the timing is uncertain.

Novo Nordisk's semaglutide patent will expire in China in 2026 while equivalent patents expire in 2031 in Japan and Europe and in 2032 in the U.S. Legal efforts are underway to strike down the Chinese patent sooner.

Upwards of 15 Chinese generic equivalents of semaglutide are racing to the market. Livzon Pharmaceutical and Jiuyan Gene already submitted separate marketing applications for generics in Type 2 diabetes. Jiuyan Gene expects approval next year but may not be able to market its product until Novo's patent expires.

Chinese companies are also developing biosimilars referencing Novo Nordisk's daily GLP-1 shot, Victoza (liraglutide). Bisoimilars by Huadong Medicine, Tonghua Dongbao Pharmaceuticals, and Sino Bio have been approved for weight loss.

In May, Eli Lilly's diabetes product, Mounjaro (terzepatide) was approved in China. Lilly's weight loss candidate, which contains the same ingredient and is known in the U.S. as Zepbound, may receive Chinese approval this or next year.

China's Innovent Biologics has inked a licensing deal with Eli Lilly for GLP-1 drug, mazdutide. The National Medical Products Administration (NMPA) of China approved the application for mazdutide's indication in chronic weight management in July. And the product could arrive on China's market in early 2025.

Meanwhile, Novo Nordisk's insulin icodec injection was recently approved by China's NMPA in Type 2 diabetes. The announcement follows approval in Europe, where it is known as Awiqli, and a request for additional data in the U.S.

El Lilly's Tirzepatide Wins Expanded Approval in China

Date: 23 Jul 2024 | #MOUNJARO #OBESITY #DIABETOLOGY #ELI LILLY #ASIA & SOUTH PACIFIC #CHINA #GLP-1 #NMPA #weight management #GIP

NAVLIN BRIEF:

- After first receiving approval from the National Medical Products Administration (NMPA) of China for diabetes in May, Eli Lilly's tirzepatide is newly approved for long-term weight management
- Known as Zepbound and Mounjaro in the U.S., tirzepatide is the first dual GIP/GLP-1 receptor agonist to launch on China's market
- Tirzepatide is a competitor to Novo Nordisk's GLP-1 agonist semaglutide which has been approved in China for diabetes since 2021 and for obesity as of last month.

THE DETAILS

BEIJING, China — Eli Lilly's tirzepatide received approval from the National Medical Products Administration (NMPA) of China for a second indication.

The one-weekly injection is newly approved in long-term weight management after receiving its first Chinese approval in May, for diabetes. It is the first dual GIP/GLP-1 receptor agonist to launch on China's market.

In the U.S., tirzepatide is approved for weight loss under the brand name Zepbound and for diabetes as Mounjaro.

The drug's first approval in China was for type 2 diabetes mellitus (T2DM) patients with poor blood glucose control after treatment with metformin or sulfonylurea drugs.

Through its dual mechanism, tirzepatide, regulates appetite. It can be used for long-term weight management for adults with a body mass index (BMI) of 28 kg/m2 (obese) through 24 kg/m2 (overweight) and at least one weight related complication (such as hypertension, dyslipidemia, hyperglycemia, obstructive sleep apnea, cardiovascular disease, etc.), in conjunction with diet and exercise.

President and General Manager, Eli Lilly China Huzur Devletsah commented in a company press release, "more than half of Chinese adults are experiencing the effects of obesity or overweight and Eli Lilly is working tirelessly to improve their health."

Tirzepatide is a competitor to Novo Nordisk's GLP-1 agonist semaglutide which has been approved in China for diabetes since 2021 and for obesity as of last month.

Due to supply limits, Novo Nordisk is planning a restrained launch of semaglutide with the help of CDMO Catalent. The company said it would first target patients in China who pay out-of-pocket.

Launch plans and pricing for tirzepatide have not been released by Eli Lilly. The drug's new approval is backed by the SURMOUNT-CN trial. The average body weight reduction at week 52 was 13.6% with tirzepatide 10 mg, 17.5% with tirzepatide 15 mg, and 2.3% with placebo. The most common treatment-emergent adverse events were gastrointestinal, with most categorized as mild to moderate in severity.

Global companies are bracing for a surge of generic weight-loss drugs expected to reach the Chinese market in the near future.

Novo Nordisk Expected to Win Semaglutide Patent Case in China

Date: 23 Jul 2024 | #SEMAGLUTIDE #OZEMPIC #WEGOVY #OBESITY #DIABETES MELLITUS (TYPE 2) #DIABETOLOGY #NOVO NORDISK #ASIA & SOUTH PACIFIC #CHINA #supreme court #GLP-1 #patent #HUADONG

NAVLIN BRIEF:

- Novo Nordisk is expected to win a case challenging its Chinese patent for GLP-1 drug semaglutide effectively staving off competition from locally developed generics
- Novo's semaglutide is approved in China for diabetes and weight management, but upwards of 15 Chinese generic equivalents are under development, along with many other GLP-1 products
- As soon as late 2024, China's Supreme Court is expected to reaffirm the validity of the company's semaglutide patent, which expires in 2026

THE DETAILS

BEIJING, China — Novo Nordisk is expected to win a case challenging its Chinese patent for GLP-1 drug semaglutide effectively staving off competition from locally developed generics.

Novo's Ozempic (semaglutide) has been approved in China for diabetes since 2021 and its other semaglutide-based drug Wegovy was approved in China for weight management in June.

The company has been preparing for competition from upwards of 15 Chinese generic equivalents of semaglutide. Many other GLP-1 products are also under development in the country for weight loss.

Eli Lilly's tirzepatide, the first dual GIP/GLP-1 receptor agonist to launch on China's market, just received approval for long-term weight management after receiving its first Chinese approval in May, for diabetes.

If proven to be effective and safe, generics on the Chinese market could reduce the price of semaglutide by about 25%, estimated analysts from Goldman Sachs. A weekly 3mL injection of Ozempic is priced at roughly $100 in China's public hospitals, said Karan Verma, an analyst from information services provider Clariva.

Generic semaglutide, however, would not have access to the Chinese market until Novo Nordisk's patent expires in 2026. In an effort to unlock the market sooner, the patent has been legally challenged.

Experts cited by MedWatch predict a legal win for Novo. The case is pending in China's Supreme Court, with a decision possible as soon as late 2024.

"The case is most likely to go in Novo Nordisk's favor. Semaglutide is a blockbuster that attracts a lot of attention around the world. At the same time, the Chinese court is leaning more and more in favor of patent holders," commented Stephen Zou, a partner at Liu, Shen & Associates, a law firm headquartered in several Chinese metropolises. With more than two decades of experience, Zou has represented large players like Takeda and Boehringer Ingelheim in other patent cases.

Confidence that Novo Nordisk would win was echoed by Patent attorney James Hou, head of Chinese patent office Cipic. "It is very likely that the Supreme Court will uphold the decision of the Beijing Patent Court," he said.

Chinese generics developer Huadong Medicines first challenged semaglutide's main patent in 2021. The case was supported by China's national patent authority, CNIPA, which agreed that the patent lacked clear evidence of the drug's attributes, such as its week-long efficacy.

After Novo filed an appeal, the patent court in Beijing ruled in its favor. The unusually forgiving decision set a historic precedent as it was based on additional data submitted by Novo.

Huadong revived the case after appealing to the highest court where Novo is represented by law firm King & Wood Mallesons. A decision may take until next year to come to fruition, estimated Danish business media group Finans.

China is Novo's second largest market, but the company's insulin sales in the country have suffered from sluggish growth rates in recent years. Given this context, Novo's semaglutide patent is important for sustaining its revenue.

Christine Zhou Xiaping, Novo's head of China, also expressed optimism while welcoming competition in March, "We believe we have a very strong competitive advantage in China because we have been present there for 30 years, so we have really built a strong, trusting partnership with external stakeholders."

Sales revenue from Ozempic and Wegovy in China is estimated by HSBC's Pharmaceutical analyst Rajesh Kumar to reach DKK 6.5bn this year and DKK 12bn by 2030.

However, TD Cowen's more skeptical analyst, Michael

Nedelkovych, said revenue could near DKK 13bn in 2025 before falling to roughly DKK 9bn in 2026 due to generic competition.

In parallel, Novo is developing a successor product which combines cagrilintide, a dual amylin and calcitonin receptor agonist, with semaglutide. It is known as CagriSema.

Saudi Arabia Mandates Pharmaco-Economic Assessments from July 2025

Date: 16 Jul 2024 | #MIDDLE EAST #SAUDI ARABIA #health technology assessment #Saudi Arabia #HTA #SFDA #economic evaluations #mandatory

NAVLIN BRIEF:

- Pharmacoeconomic assessments are set to become mandatory in Saudi Arabia starting from July 2025. The Saudi Food and Drug Authority (SFDA) will require manufacturers to submit a budget-impact analysis or a type of cost analysis (-effectiveness, -minimization, -utility, or -benefit), as well as a market share and marketing plan alongside these assessments
- Additionally, decisions made by other HTA bodies like the National Institute for Health and Care Excellence (NICE), Canada's Drug Agency (CDA), and France's High Health Authority (HAS) will play a significant role, as the SFDA now mandates companies to submit data from these HTA assessment bodies, with CDA being particularly influential
- Manufacturers must be meticulous in preparing and submitting relevant data according to these new requirements for a successful application. This is a change from the previous system, where omissions in price certificate forms could be negotiated during the appeals process to achieve a final price

THE DETAILS

RIYADH, Saudi Arabia—Pharmaco-economic assessments will be mandatory in Saudi Arabia from July 2025. These kinds of assessments were previously supplementary (for example, companies could submit a budget impact analysis to justify a higher price or to align with comparator or international reference price (IRP) prices) but will be made compulsory from the implementation date.

The SFDA will also accept managed entry agreements, such as incentive agreements, patient support programs, and breakthrough designation agreements, upon registration.

Additionally, existing influential health technology assessment (HTA) outcomes will be required and will play a stronger role in pricing decisions. This refers to decisions made by other HTA bodies like the National Institute for Health and Care Excellence (NICE), Canada's Drug Agency (CDA), and France's High Health Authority (HAS), which will play a significant role. The SFDA now mandates companies to submit data from these HTA assessment bodies, with CDA being particularly influential, according to NAVLIN Market Access Analyst Aatiqah Thanvi.

Additionally, manufacturers will need to submit a market share and marketing plan, providing the expected market share volume for the upcoming five years and a detailed marketing plan for launching in Saudi Arabia. This will be mandatory as part of the price certificate form. Previously, this information was optional but will now be strictly enforced.

The drug marketing plan refers to the targeted segment of healthcare in Saudi Arabia that the product is mainly distributed in. Information on the targeted segment should be presented in the submission file to the SFDA. It could be one or more of the following:

Distribution in:	
i.	Tender Item only
ii.	Retail Pharmacy only
iii.	Public (whole market)

Prescription Type:	
i.	Hospital item only
ii.	Restricted
iii.	Controlled
iv.	Over the Counter (OTC)

From July 2025, the following types of assessments will be accepted:

- Budget Impact Analysis (preferred)
- Cost-Effectiveness Analysis (preferred after budget-impact, currently used in certain hospitals to allow reimbursement)
- Cost-Minimization Analysis
- Cost-Utility Analysis
- Cost-Benefit Analysis

Years/Data requirements	General Requirements	Economic Evaluation Requirements
July-December 2024	Voluntary	Voluntary
January-June 2025	Mandatory	Voluntary
July 2025	Mandatory	Mandatory

Inclusions

Full Economic Evaluations Studies (EES's) must include:

- Study objective: The study objective(s) should be clearly stated, including research questions for each goal.
- Targeted population: The specifications of the targeted population should be included. Sub-group analyses are encouraged.
- Perspective of analysis: The viewpoint of the study should be indicated. A healthcare payer and/or societal perspective should be indicated in EES are sufficient for the evaluation.
- Time horizon: The length of the study should include the natural disease history or encapsulate all differences either in cost or outcomes.
- Comparator: The comparator should be drawn from the current standard of practice. This should include the least expensive and most effective treatments available. Inclusion of emerging technologies is encouraged.
- The estimated threshold: The current estimated cost-effectiveness threshold published in Saudi Arabia ranges between SAR 50,000 – 75,000 per QALY. However, consideration will be taken for specific products.
- Modeling: The details of the model utilized and justifications for using it should be included. Validation of the model is encouraged to be provided. Parameterization should be applied to the global models by changing the main key parameters to meet SFDA's requirements in case no local economic model is available.
- Costs calculations: All relevant costs determined by perspective choice should to be included. The direct healthcare costs are required to be included at least. Intangible costs are encouraged to be provided when adapt societal perspective.
- Long-term care and productivity loss costs: The costs resulted from a long period of patient care or inability to work during illness are encouraged to be included in the analysis. The method for calculating these costs is required to be included.
- Outcomes measurement: The evaluation should clearly state the outcome effectiveness measurement. The relevant outcome measure is chosen based on the type of analysis. Utility measurement is required to be included if CUA is submitted.
- Additional benefit in efficacy or safety: The evaluation should highlight the new health technology's additional benefit in either safety or efficacy. Effectiveness data resulting from Real-World Evidence (RWE) are encouraged to be submitted.
- Sources of cost or clinical data: All sources of data used in the evaluation should be included. Cost data should be retrieved from Saudi Arabia healthcare system, while clinical data retrieved from Randomized Controlled Trial (RCT) and RWE, and/or Network Meta-Analysis (NMA).
- Discounting: This is the monetary value and outcomes' depreciation over time. The yearly discount rate is 3%—5%. It is mandatory to include it for cost calculations at least. The 3-5% rate represents the assumption of the prices taken in the health economic studies, as it's fair to use an erosion of 3-5% year over year in the study.
- Uncertainty and sensitivity analysis: All uncertainties (Parametric, methodological and Structural) in the base-case scenario should be addressed in the sensitivity analyses. Probabilistic Sensitivity Analyses (PSA) is preferred to be used in the evaluation. Deterministic Sensitivity Analysis (DSA) should be provided including one-way sensitivity analysis (preferred) and, multiway sensitivity analysis with scenario sensitivity analysis (if feasible).
- Presentation of results: Results of the base case should be presented in cost-outcomes increments demonstrated in the cost-effectiveness plane. For PSA and DSA, the result should be depicted in a cost effectiveness acceptability curve with scatter plot and tornado diagram, respectively. Results of BIA should be presented in table format
- Data Source, Equity and generalizability to Saudi Arabia: The data in the evaluation should be applicable to generalize it to Saudi Arabia with all patients having a fair opportunity for participation and for obtaining the expected treatment outcomes. Equity and fairness in distribution should be taken into consideration.
- Other: Conflicts of interests and funding should be reported if any.

However, for a partial EEC, only a study objective, targeted population, perspective of analysis, time horizon, comparator, uncertainty and sensitivity analysis, presentation of results and other relevant info such as conflict of interest should be included.

Full details of the new requirements can be found in this document, published by the SFDA.

These changes underscore the SFDA's commitment to moving toward comprehensive and transparent economic evaluations for all pharmaceutical products. It is imperative that all relevant data be meticulously prepared and submitted according to these new requirements, to ensure successful application.

Previously price certificate forms were taken informally, and it was generally considered acceptable if manufacturers missed a section, as the appeals process and further negotiation with key stakeholders within the SFDA could help achieve the final price. Going forward, however, this is not the case.

The move follows a recent update to Saudi's regulatory framework.

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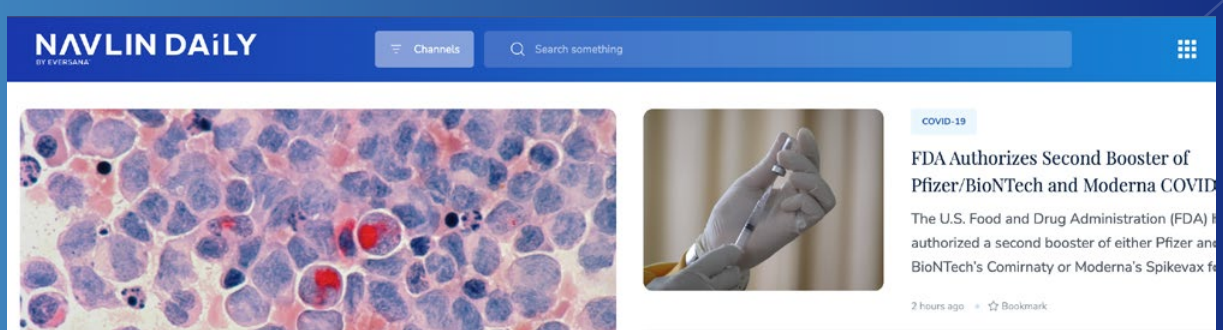

HTAs, Approvals, Launches & Price Changes

HTAs: France

- SPINRAZA; NUSINERSEN; BIOGEN; SPINAL MUSCULAR ATROPHY (PEDIATRIC); Paediatric patients who are presymptomatic and having 2 to 3 copies of the SMN2 gene.; SMR (IMPORTANT); ASMR III (MODERATE); RECOMMENDED
- SPINRAZA; NUSINERSEN; BIOGEN; SPINAL MUSCULAR ATROPHY; Patients with 5q type 1 disease.; SMR (IMPORTANT); ASMR III (MODERATE); RECOMMENDED
- SPINRAZA; NUSINERSEN; BIOGEN; SPINAL MUSCULAR ATROPHY; Patients with 5q type 2 disease.; SMR (IMPORTANT); ASMR III (MODERATE); RECOMMENDED
- SPINRAZA; NUSINERSEN; BIOGEN; SPINAL MUSCULAR ATROPHY; Patients with 5q type 3 disease.; SMR (IMPORTANT); ASMR V (ABSENCE); RECOMMENDED
- ARTESUNATE; ARTESUNATE; AMIVAS; MALARIA; Adult patients; SMR (IMPORTANT); ASMR III (MODERATE); RECOMMENDED
- ARTESUNATE; ARTESUNATE; AMIVAS; MALARIA (PEDIATRIC); Children patients; SMR (IMPORTANT); ASMR III (MODERATE); RECOMMENDED
- RYEQO; RELUGOLIX & ESTRADIOL & NORETHISTERONE; GEDEON RICHTER; ENDOMETRIOSIS; Adult women patients who are of childbearing age, who have a history of medical or surgical treatment for the same disease and are currently undergoing symptomatic treatment.; SMR (IMPORTANT); ASMR V (ABSENCE); RECOMMENDED
- FINLEE; DABRAFENIB; NOVARTIS; LOW-GRADE GLIOMA (BRAF V600 MUTATION-TRAMETINIB) (PEDIATRIC); Paediatric patients aged 1 year and older who require systemic therapy.; SMR (IMPORTANT); ASMR IV (MINOR); RECOMMENDED
- FINLEE; DABRAFENIB; NOVARTIS; HIGH-GRADE GLIOMA (BRAF V600E MUTATION-TRAMETINIB) (PEDIATRIC); Paediatric patients aged 1 year and older who have received at least one prior course of radiation therapy and/or chemotherapy.; SMR (IMPORTANT); ASMR IV (MINOR); RECOMMENDED
- COLUMVI; GLOFITAMAB; ROCHE; DIFFUSE LARGE B-CELL LYMPHOMA (RELAPSED/REFRACTORY); Adult patients who received at least two lines of systemic treatment, ineligible for all available treatments or who have failed CAR-T cell-based drugs.; SMR (IMPORTANT); RECOMMENDED
- CASGEVY; EXAGAMGLOGENE AUTOTEMCEL; VERTEX; SICKLE CELL DISEASE; Paediatric patients aged 12 years and older, who are with recurrent vaso-occlusive crises (VOCs) despite adequate treatment with hydroxycarbamide and who are eligible for a haematopoietic stem cell transplant (HSCT), and for whom a compatible HLA (human leukocyte antigen) related donor is not available, and whose disease severity is established by the implementation of a transfusion program for at least 6 months for recurrent vaso-occlusive episodes.; SMR (IMPORTANT); RECOMMENDED
- CASGEVY; EXAGAMGLOGENE AUTOTEMCEL; VERTEX; SICKLE CELL DISEASE; Adult patients aged less than 35, who are with recurrent vaso-occlusive crises (VOCs) despite adequate treatment with hydroxycarbamide and who are eligible for a haematopoietic stem cell transplant (HSCT), and for whom a compatible HLA (human leukocyte antigen) related donor is not available, and whose disease severity is established by the implementation

of a transfusion program for at least 6 months for recurrent vaso-occlusive episodes.; SMR (IMPORTANT); RECOMMENDED

- CASGEVY; EXAGAMGLOGENE AUTOTEMCEL; VERTEX; SICKLE CELL DISEASE; Adult patients aged less than 35, who are with recurrent vaso-occlusive crises (VOCs) despite adequate treatment with hydroxycarbamide and who are eligible for a haematopoietic stem cell transplant (HSCT), and for whom a compatible HLA (human leukocyte antigen) related donor is not available, and whose disease severity is established by the persistence of recurrent vaso-occlusive episodes requiring conventional hospitalization within the year (≥ 2 episodes/year or ≥ 1 episode/year requiring a transfusion).; SMR (IMPORTANT); RECOMMENDED
- RYBREVANT; AMIVANTAMAB; JOHNSON & JOHNSON INNOVATIVE MEDICINE; NSCLC (EGFR-EXON 19 DELETION OR EXON 21 L858R MUTATION-POSITIVE) (PEMETREXED AND PLATINUM-BASED CHEMOTHERAPY); Adult patients who have failed a previous treatment including a third generation EGFR tyrosine kinase inhibitor (TKI).; SMR (IMPORTANT); RECOMMENDED
- BRUKINSA; ZANUBRUTINIB; BEIGENE; FOLLICULAR LYMPHOMA (OBINUTUZUMAB); Adult patients who have received at least two prior systemic treatments.; SMR (INSUFFICIENT); NOT RECOMMENDED
- EMBLAVEO; AVIBACTAM & AZTREONAM; PFIZER; COMPLICATED INTRA ABDOMINAL INFECTIONS; Adult patients whose infections caused by Enterobacteriaceae with a resistance mechanism of the metallo-β-lactamase type (NDM, VIM, IMP) or Stenotrophomonas maltophilia, sensitive to the aztreonam/avibactam combination, and for whom recourse to other available antibiotics is not appropriate in the event of resistance.; SMR (IMPORTANT); RECOMMENDED
- EMBLAVEO; AVIBACTAM & AZTREONAM; PFIZER; NOSOCOMIAL PNEUMONIA; Adult patients whose infections caused by Enterobacteriaceae with a resistance mechanism of the metallo-β-lactamase type (NDM, VIM, IMP) or Stenotrophomonas maltophilia, sensitive to the aztreonam/avibactam combination, and for whom recourse to other available antibiotics is not appropriate in the event of resistance.; SMR (IMPORTANT); RECOMMENDED
- EMBLAVEO; AVIBACTAM & AZTREONAM; PFIZER; VENTILATOR-ASSOCIATED PNEUMONIA; Adult patients whose infections caused by Enterobacteriaceae with a resistance mechanism of the metallo-β-lactamase type (NDM, VIM, IMP) or Stenotrophomonas maltophilia, sensitive to the aztreonam/avibactam combination, and for whom recourse to other available antibiotics is not appropriate in the event of resistance.; SMR (IMPORTANT); RECOMMENDED
- EMBLAVEO; AVIBACTAM & AZTREONAM; PFIZER; COMPLICATED URINARY TRACT INFECTIONS; Adult patients whose infections caused by Enterobacteriaceae with a resistance mechanism of the metallo-β-lactamase type (NDM, VIM, IMP) or Stenotrophomonas maltophilia, sensitive to the aztreonam/avibactam combination, and for whom recourse to other available antibiotics is not appropriate in the event of resistance.; SMR (IMPORTANT); RECOMMENDED
- EMBLAVEO; AVIBACTAM & AZTREONAM; PFIZER; PYELONEPHRITIS; Adult patients whose infections caused by Enterobacteriaceae with a resistance mechanism of the metallo-β-lactamase type (NDM, VIM, IMP) or Stenotrophomonas maltophilia, sensitive to the aztreonam/avibactam combination, and for whom recourse to other available antibiotics is not appropriate in the event of resistance.; SMR (IMPORTANT); RECOMMENDED
- EMBLAVEO; AVIBACTAM & AZTREONAM; PFIZER; BACTERIAL INFECTIONS (AEROBIC); Adult patients whose infection is due to Gram-negative aerobic bacteria and for whom therapeutic options are limited.; SMR (IMPORTANT); RECOMMENDED

HTAs: Germany

- ELREXFIO; ELRANATAMAB; PFIZER; MULTIPLE MYELOMA (RELAPSED OR REFRACTORY); Adults who have received three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, and who have shown disease progression during the last therapy.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED

- ELREXFIO; ELRANATAMAB; PFIZER; MULTIPLE MYELOMA (RELAPSED OR REFRACTORY); Adults who have received at least 4 prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, and who have shown disease progression during the last therapy.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- EVKEEZA; EVINACUMAB; ULTRAGENYX; HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA; Adolescents aged 12 years and over in whom dietary and medicinal options for lipid-lowering have been exhausted.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- EVKEEZA; EVINACUMAB; ULTRAGENYX; HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA; Adults in whom dietary and medicinal options for lipid-lowering have been exhausted.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- LOARGYS; PEGZILARGINASE; IMMEDICA PHARMA; HYPERARGININEMIA; Adult patients; NON-QUANTIFIABLE ADDITIONAL BENEFIT; RECOMMENDED
- LOARGYS; PEGZILARGINASE; IMMEDICA PHARMA; HYPERARGININEMIA; Adolescent patients; NON-QUANTIFIABLE ADDITIONAL BENEFIT; RECOMMENDED
- LOARGYS; PEGZILARGINASE; IMMEDICA PHARMA; HYPERARGININEMIA (PEDIATRIC); Children aged 2 years and above; NON-QUANTIFIABLE ADDITIONAL BENEFIT; RECOMMENDED
- EVKEEZA; EVINACUMAB; ULTRAGENYX; HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (PEDIATRIC); Children in whom dietary and medicinal options for lipid-lowering have been exhausted.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- EVKEEZA; EVINACUMAB; ULTRAGENYX; HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA; Adolescents aged 5 to < 12 years in whom dietary and medicinal options for lipid-lowering have been exhausted.; NO ADDITIONAL BENEFIT OVER COMPARATOR; RECOMMENDED
- AGAMREE; VAMOROLONE; SANTHERA; DUCHENNE MUSCULAR DYSTROPHY; Patients aged 4 years and older.; NON-QUANTIFIABLE ADDITIONAL BENEFIT; RECOMMENDED

HTAs: Italy

- COVERSYL; PERINDOPRIL; SERVIER; HEART FAILURE; RECOMMENDED
- COVERSYL; PERINDOPRIL; SERVIER; HYPERTENSION; RECOMMENDED
- COVERSYL; PERINDOPRIL; SERVIER; PREVENTION OF CARDIOVASCULAR COMPLICATIONS; RECOMMENDED
- COVERSYL; PERINDOPRIL; SERVIER; HEART FAILURE; RECOMMENDED
- COVERSYL; PERINDOPRIL; SERVIER; HYPERTENSION; RECOMMENDED
- COVERSYL; PERINDOPRIL; SERVIER; PREVENTION OF CARDIOVASCULAR COMPLICATIONS; RECOMMENDED
- DESMOPRESSIN; DESMOPRESSIN; ZENTIVA; POST-HYPOPHYSECTOMY POLYURIA/POLYDIPSIA; RECOMMENDED
- DESMOPRESSIN; DESMOPRESSIN; ZENTIVA; CRANIAL DIABETES INSIPIDUS; RECOMMENDED
- DESMOPRESSIN; DESMOPRESSIN; ZENTIVA; NOCTURNAL ENURESIS; RECOMMENDED

- LYRICA; PREGABALIN; UPJOHN; NEUROPATHIC PAIN; Adult patients; RECOMMENDED
- LYRICA; PREGABALIN; UPJOHN; ANXIETY DISORDER; Adult patients; RECOMMENDED
- LYRICA; PREGABALIN; UPJOHN; EPILEPSY; Adult patients; RECOMMENDED
- LYRICA; PREGABALIN; UPJOHN; POSTHERPETIC NEURALGIA; Adult patients; RECOMMENDED
- LYRICA; PREGABALIN; UPJOHN; GENERALISED ANXIETY DISORDER; Adult patients; RECOMMENDED
- LYRICA; PREGABALIN; UPJOHN; PARTIAL SEIZURES (ADJUNCTIVE THERAPY); Adult patients; RECOMMENDED
- LYRICA; PREGABALIN; UPJOHN; NEUROPATHIC PAIN; Adult patients; RECOMMENDED
- LYRICA; PREGABALIN; UPJOHN; ANXIETY DISORDER; Adult patients; RECOMMENDED
- LYRICA; PREGABALIN; UPJOHN; EPILEPSY; Adult patients; RECOMMENDED
- LYRICA; PREGABALIN; UPJOHN; GENERALISED ANXIETY DISORDER; Adult patients; RECOMMENDED
- LYRICA; PREGABALIN; UPJOHN; PARTIAL SEIZURES (ADJUNCTIVE THERAPY); Adult patients; RECOMMENDED
- LYRICA; PREGABALIN; UPJOHN; NEUROPATHIC PAIN; Adult patients; RECOMMENDED

HTAs: Spain

- OPDIVO; NIVOLUMAB; BRISTOL MYERS SQUIBB; METASTATIC MELANOMA (ADJUVANT TREATMENT); Adult patients who have undergone complete resection.; CONDITIONALLY RECOMMENDED
- OPDIVO; NIVOLUMAB; BRISTOL MYERS SQUIBB; METASTATIC MELANOMA (ADJUVANT TREATMENT); Adolescent patients aged 12 years and older who have undergone complete resection.; CONDITIONALLY RECOMMENDED
- XARELTO; RIVAROXABAN; BAYER; PREVENTION OF CARDIOVASCULAR COMPLICATIONS (CAD); Adult patients with coronary heart disease at high risk of developing ischemic events.; NOT RECOMMENDED
- XARELTO; RIVAROXABAN; BAYER; PREVENTION OF CARDIOVASCULAR COMPLICATIONS (PAD); Adult patients with symptomatic peripheral arterial disease at high risk of developing ischemic events.; NOT RECOMMENDED
- JARDIANCE; EMPAGLIFLOZIN; BOEHRINGER INGELHEIM; CHRONIC KIDNEY DISEASE; Adult patients.; CONDITIONALLY RECOMMENDED
- PEPAXTI; MELPHALAN FLUFENAMIDE; ONCOPEPTIDES; MULTIPLE MYELOMA (REFRACTORY) (COMBINATION); Adult patients who have received at least three lines of previous treatments, whose disease is resistant to at least one proteasome inhibitor, a drug immunomodulator and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression during or after the last treatment.; RECOMMENDED

HTAs: UK

- EBGLYSS; LEBRIKIZUMAB; ALMIRALL; ATOPIC DERMATITIS; Patients aged 12 years and over with a body weight of 40 kg or more, who are suitable for systemic treatment.; CONDITIONALLY RECOMMENDED
- METALYSE; TENECTEPLASE; BOEHRINGER INGELHEIM; ISCHEMIC STROKE; Adult patients who are within 4.5 hours of the onset of stroke symptoms, and when intracranial haemorrhage has been excluded.; RECOMMENDED

- HEMGENIX; ETRANACOGENE DEZAPARVOVEC; CSL BEHRING; HAEMOPHILIA B; Adult patients without anti-FIX antibodies.; RECOMMENDED
- KAFTRIO; IVACAFTOR & TEZACAFTOR & ELEXACAFTOR; VERTEX; CYSTIC FIBROSIS; People 2 years and over who have at least 1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.; RECOMMENDED
- SYMKEVI; IVACAFTOR & TEZACAFTOR; VERTEX; CYSTIC FIBROSIS; People 6 years and over who have 2 copies of the CFTR gene with F508del mutations.; RECOMMENDED
- SYMKEVI; IVACAFTOR & TEZACAFTOR; VERTEX; CYSTIC FIBROSIS; People 6 years and over who have a copy of the CFTR gene with an F508del mutation and a copy of the CFTR gene with 1 of the mutations listed: P67L, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G, and 3849+10kbC→T'.; RECOMMENDED
- ORKAMBI; IVACAFTOR & LUMACAFTOR; VERTEX; CYSTIC FIBROSIS; People 1 year and over who have 2 copies of the CFTR gene with F508del mutations.; RECOMMENDED
- ENHERTU; TRASTUZUMAB DERUXTECAN; DAIICHI SANKYO; BREAST CANCER (HER2-LOW); Adult patients who have had chemotherapy in the metastatic setting.; NOT RECOMMENDED
- ENHERTU; TRASTUZUMAB DERUXTECAN; DAIICHI SANKYO; BREAST CANCER (HER2-LOW); Adult patients who have had recurrence during adjuvant chemotherapy or within 6 months after finishing it.; NOT RECOMMENDED

Approvals: China

- AVATROMBOPAG MALEATE; AVATROMBOPAG MALEATE; GYRE THERAPEUTICS; THROMBOCYTOPENIA (CHRONIC LIVER DISEASE)
- EFGARTIGIMOD SC; EFGARTIGIMOD ALFA; ZAI LAB AND ARGENX; GENERALIZED MYASTHENIA GRAVIS

Approvals: EU

- DURVEQTIX; FIDANACOGENE ELAPARVOVEC; PFIZER EUROPE MA EEIG; HAEMOPHILIA B
- AVZIVI; BEVACIZUMAB; FGK REPRESENTATIVE SERVICE GMBH; COLORECTAL CANCER,NSCLC, BREAST CANCER, RENAL CELL CARCINOMA, CERVICAL CANCER, OVARIAN CANCER
- CEJEMLY; SUGEMALIMAB; SFL PHARMACEUTICALS DEUTSCHLAND GMBH; NSCLC
- FYMSKINA; USTEKINUMAB; FORMYCON AG; PSORIASIS, PSORIATIC ARTHRITIS, CROHN'S DISEASE AND ULCERATIVE COLITIS
- TUZNUE; TRASTUZUMAB; PRESTIGE BIOPHARMA BELGIUM; BREAST CANCER AND GASTRIC CANCER
- KAYFANDA; ODEVIXIBAT; IPSEN PHARMA; PRURITUS
- ANZUPGO; DELGOCITINIB; LEO PHARMA A/S; DERMATITIS AND ECZEMA
- EKSUNBI; USTEKINUMAB; SAMSUNG BIOEPIS NL B.V.; PSORIASIS, PSORIATIC ARTHRITIS, CROHN'S DISEASE AND ULCERATIVE COLITIS
- VYLOY; ZOLBETUXIMAB; ASTELLAS PHARMA EUROPE B.V.; GASTRIC OR GASTRO-OESOPHAGEAL JUNCTION ADENOCARCINOMA
- OTULFI; USTEKINUMAB; FRESENIUS KABI DEUTSCHLAND GMBH; PSORIASIS, PSORIATIC ARTHRITIS, CROHN'S DISEASE

- LOQTORZI; TORIPALIMAB; TMC PHARMA (EU) LIMITED; NASOPHARYNGEAL CARCINOMA AND OESOPHAGEAL SQUAMOUS CELL CARCINOMA
- VEVIZYE; CICLOSPORIN; NOVALIQ GMBH; SEVERE DRY EYE
- IQIRVO; ELAFIBRANOR; IPSEN PHARMA; PRIMARY BILIARY CHOLANGITIS
- YUVANCI; MACITENTAN & TADALAFIL; JANSSEN-CILAG INTERNATIONAL NV; PULMONARY ARTERIAL HYPERTENSION
- ITUXREDI; RITUXIMAB; REDDY HOLDING GMBH; NON-HODGKIN'S LYMPHOMA, STAGE III-IV FOLLICULAR LYMPHOMA, DIFFUSE LARGE B CELL NON-HODGKIN'S LYMPHOMA, DIFFUSE LARGE B-CELL LYMPHOMA, BURKITT LYMPHOMA, CLL, RHEUMATOID ARTHRITIS, GRANULOMATOSIS WITH POLYANGIITIS AND MICROSCOPIC POLYANGIITIS, PEMPHIGUS VULGARIS
- RANIBIZUMAB MIDAS; RANIBIZUMAB; MIDAS PHARMA GMBH; AMD, DME, RVO, CNV AND DIABETIC RETINOPATHY

Approvals: U.S.

- PYZCHIVA; USTEKINUMAB-TTWE; SANDOZ; PLAQUE PSORIASIS, PSORIATIC ARTHRITIS, CROHN'S DISEASE AND ULCERATIVE COLITIS
- KISUNLA; DONANEMAB-AZBT; ELI LILLY CO; ALZHEIMER'S DISEASE
- VASOPRESSIN IN SODIUM CHLORIDE INJECTION; VASOPRESSIN; LONG GROVE PHARMS; HYPOTENSION
- EPYSQLI; ECULIZUMAB-AAGH; SAMSUNG BIOEPIS CO LTD; PAROXYSMAL NOCTURNAL HEMOGLOBINURIA AND HEMOLYTIC UREMIC SYNDROME
- ZITUVIMET XR; SITAGLIPTIN & METFORMIN; ZYDUS WORLDWIDE DMCC; DIABETES MELLITUS TYPE 2
- FEMLYV; NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL; MILLICENT PUERTO RICO LLC; CONTRACEPTION
- ZUNVEYL; BENZGALANTAMINE; ALPHA COGNITION INC; DEMENTIA WITH ALZHEIMER'S DISEASE
- LEQSELVI; DEURUXOLITINIB; SUN PHARM INDS; ALOPECIA AREATA
- ERZOFRI; PALIPERIDONE PALMITATE; LUYE PHARMA; SCHIZOPHRENIA, SCHIZOAFFECTIVE DISORDER

Germany: Post-AMNOG Price Changes for Originator Drugs

PRODUCT GROUP	GENERIC NAME	DESCRIP	START DATE	MNF (EUR)	OLD MNF PRICE	MNF AMOUNT CHANGE	MNF PERCENT CHANGE	MNF (USD)	OLD MNF PRICE	MNF AMOUNT CHANGE	MNF PERCENT CHANGE
DUPIXENT	DUPILUMAB	DUPIXENT INJECTION 2 PREFILLED PEN 1.14 ML 200 MG	07/01/24	1047.22	1056.96	-9.74	-0.92%	1145.68	1156.34	-10.66	-0.92%
JANUMET	METFORMIN & SITAGLIPTIN	JANUMET TABLETS 1 PACK 196 TABS 50 MG/1000 MG	07/01/24	86.42	86.40	+0.02	+0.02%	94.55	94.53	+0.02	+0.02%
KIMMTRAK	TEBENTAFUSP	KIMMTRAK INJECTION 1 VIAL 0.5 ML 100 MCG	07/15/24	9900.00	10000.00	-100.00	-1.00%	10830.80	10940.20	-109.40	-1.00%
KISQALI	RIBOCICLIB	KISQALI TABLETS 1 PACK 21 TABS 200 MG	07/15/24	1816.15	1821.84	-5.69	-0.31%	1986.90	1993.12	-6.22	-0.31%
ONUREG	AZACITIDINE	ONUREG TABLETS 1 PACK 14 TABS 200 MG	07/01/24	15173.14	14327.80	+845.34	+5.90%	16599.72	15674.90	+924.82	+5.90%
ONUREG	AZACITIDINE	ONUREG TABLETS 1 PACK 14 TABS 300 MG	07/01/24	15173.14	14327.80	+845.34	+5.90%	16599.72	15674.90	+924.82	+5.90%
ONUREG	AZACITIDINE	ONUREG TABLETS 1 PACK 7 TABS 200 MG	07/01/24	7586.57	7163.90	+422.67	+5.90%	8299.86	7837.45	+462.41	+5.90%
ONUREG	AZACITIDINE	ONUREG TABLETS 1 PACK 7 TABS 300 MG	07/01/24	7586.57	7163.90	+422.67	+5.90%	8299.86	7837.45	+462.41	+5.90%
TECFIDERA	DIMETHYL FUMARATE	TECFIDERA CAPSULES 1 PACK 14 CAPS 120 MG	07/01/24	91.39	91.48	-0.09	-0.10%	99.98	100.08	-0.10	-0.10%
TECFIDERA	DIMETHYL FUMARATE	TECFIDERA CAPSULES 1 PACK 168 CAPS 240 MG	07/01/24	2193.35	2195.42	-2.07	-0.09%	2399.57	2401.83	-2.26	-0.09%
TECFIDERA	DIMETHYL FUMARATE	TECFIDERA CAPSULES 1 PACK 56 CAPS 240 MG	07/01/24	731.12	731.81	-0.69	-0.09%	799.86	800.61	-0.75	-0.09%

**7 other presentations of DUPIXENT had similar price changes*

Price Changes: Europe & U.S.

COUNTRY	GENERIC NAME	PRODUCT GROUP	COMPANY	THERAPEUTIC AREA	AVG. PRICE CHANGE ALL SKU
FRANCE	CERTOLIZUMAB PEGOL	CIMZIA	UCB	IMMUNOSUPPRESSANTS	-4.85%
FRANCE	USTEKINUMAB	STELARA	JOHNSON & JOHNSON INNOVATIVE MEDICINE	IMMUNOSUPPRESSANTS	-10.53%
ITALY (PRIVATE)	FORMOTEROL & BUDESONIDE	SYMBICORT	ASTRAZENECA	RESPIRATORY	-8.63%
SPAIN	TIMOLOL & TRAVOPROST	DUOTRAV	NOVARTIS	OPHTHALMOLOGY	-9.16%
SPAIN	PILOCARPINE	SALAGEN	ROVI	NEUROLOGY	-40.01%
UNITED KINGDOM	RELUGOLIX	ORGOVYX	ACCORD	ONCOLOGY	-41.76%
UNITED STATES	AVELUMAB	BAVENCIO	EMD SERONO	ONCOLOGY	3.00%
UNITED STATES	RISANKIZUMAB	SKYRIZI	ABBVIE	IMMUNOSUPPRESSANTS	3.20%
UNITED STATES	ATEZOLIZUMAB	TECENTRIQ	GENENTECH	ONCOLOGY	3.00%

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	MAVACAMTEN	CAMZYOS	BRISTOL MYERS SQUIBB	HYPERTROPHIC CARDIOMYOPATHY	CVS	06/26/2023	07/12/2024
FRANCE	USTEKINUMAB	UZPRUVO	EG LABO	PSORIASIS, PSORIATIC ARTHRITIS, CROHN'S DISEASE	IMMUNOSUPPRESSANTS	01/05/2024	07/18/2024
GERMANY	IPTACOPAN	FABHALTA	NOVARTIS	PAROXYSMAL NOCTURNAL HEMOGLOBINURIA	IMMUNOSUPPRESSANTS	05/17/2024	07/01/2024
GERMANY	FRUQUINTINIB	FRUZAQLA	TAKEDA	COLORECTAL CANCER	ONCOLOGY	06/20/2024	07/15/2024
SPAIN	FEZOLINETANT	VEOZA	ASTELLAS	VASOMOTOR SYMPTOMS	GYNECOLOGY	12/07/2023	07/01/2024
UNITED KINGDOM	ETRANACOGENE DEZAPARVOVEC	HEMGENIX	CSL BEHRING	HAEMOPHILIA B	BLOOD AND BLOOD FORMING ORGANS	12/20/2023	07/03/2024
UNITED STATES	DONANEMAB	KISUNLA	ELI LILLY	ALZHEIMER'S DISEASE	NEUROLOGY	07/02/2024	07/02/2024

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