PRICENTRIC ONE
BY EVERSANA™

INSIGHTS Newsletter

Issue 22 | February 2021

PBMs Again Under Fire Following Senate Report on "Surging" Insulin Costs

A recent report from the Senate Finance Committee has highlighted how pharmacy benefit managers (PBMs) have been using lock stepping, or "shadow pricing", tactics which ultimately resulted in Americans paying more for insulin at pharmacies.

Zynteglo Roll-out Hit by Double Blow: EU Suspension and NICE Rejection in Past Month

bluebird bio has suspended its roll-out of Zynteglo pending investigation of a safety concern, according to the EMA, in the same month that the United Kingdom's HTA body gave it the cold shoulder for reimbursement on the NHS.

Vertex's Kaftrio Plus Kalydeco Offers Considerable Added Benefit, Finds G-BA

Germany's G-BA has concluded that Vertex's Kaftrio plus Kalydeco offers significant benefit versus other options, including Vertex's own Symkevi, for patients aged 12 years and up with cystic fibrosis (CF) who are either homozygous or heterozygous for the F508del mutation in the CFTR gene.

Table of Contents

(Click on title to jump to page)

PBMs Again Under Fire Following Senate Report on "Surging" Insulin Costs

A recent report from the Senate Finance Committee has highlighted how pharmacy benefit managers (PBMs) have been using lock stepping, or "shadow pricing", tactics which ultimately resulted in Americans paying more for insulin at pharmacies. The report also heavily scrutinizes the wider practices of PBMs, but various organizations have rejected the findings, saying PBMs have stepped up their efforts to help patients with diabetes by introducing new programs to cap or eliminate out-of-pocket costs.

THE DETAILS

WASHINGTON, D.C., The United States – In January, the Senate Finance Committee released the results from its two-year investigation into the allegedly "surging" list price of insulin in the United States and its impact on patients, Medicare Part D, and private health plans.

The Senate's report was announced shortly before newly-inaugurated U.S. President Joseph Biden issued a 60-day halt on drug pricing rules introduced by former President Donald Trump, in particular, the requirement for community health centers to pass on savings to low-income patients for insulin and EpiPens.

It is now being delayed until March 22, 2021.

During its investigation, the Committee reviewed over 100,000 pages of internal documents, memoranda, and rebate agreements from three of the largest insulin manufacturers and three largest pharmacy benefit managers (PBMs). More than 1,700 pages of documents containing emails, contracts, and presentations that were used in the investigation will be released, the Committee said.

Committee investigators determined that insulin manufacturers raised prices despite no new advances in the efficacy of these products, and the Committee alleged the use of lock stepping – or "shadow pricing" – tactics among relevant companies, which resulted in customers paying more for insulin at pharmacies.

The investigators also concluded that neither pharmaceutical companies nor PBMs made attempts to prevent insulin price increases to avoid any changes to the current rebate structure practiced in the U.S. As noted by the Committee, "… higher list prices meant higher revenue for PBMs, and … lowering list prices could be viewed negatively by PBMs and health plans, even though it meant higher out-of-pocket costs for patients."

Other key findings from the investigation more heavily scrutinize the practices of PBMs. The Committee claims the three largest PBMs have significant market power and despite their use of exclusion lists to pressure companies to increase rebates, little has been accomplished when it comes to reducing the list price of insulin. Moreover, PBMs increased administrative fees, adding another major source of revenue for them that benefits from list price increases and the "price protection" clauses utilized by PBMs in contracts allow drug manufacturers to increase prices by 12% per year.

Grassley, Wyden Say Consumers Are Losing Out

The report was presented by Finance Committee Chairperson Chuck Grassley (R-IA) and Ranking Member Ron Wyden (D-OR), who were responsible for a previous reform bill that would rein in the costs of insulin by capping seniors' out-of-pocket (OOP) spending and limiting price increases. However, the bill died before being called for a vote in the Senate due to a lack of bipartisan support.

Regarding the report, Grassley commented, "We found that the business practices of and the competitive relationships between manufacturers and middlemen have created a vicious cycle of price increases that have sent costs for patients and taxpayers through the roof. This industry is anything but a free market when PBMs spur drugmakers to hike list prices in order to secure prime formulary placement and greater rebates and fees."

Wyden added, "This investigation makes clear that consumers are the only ones losing out in America's broken drug pricing system, since every part of the pharmaceutical supply chain benefits from higher list prices. Insulin manufacturers lit the fuse on skyrocketing prices by matching each other's price increases step for step rather than competing to lower them, while PBMs, acting as middlemen for insurers, fanned the flames to take a bigger cut of the secret rebates and hidden fees they negotiate. Consolidation within the PBM industry has not improved the situation."

PBMs, PhRMA Argue Findings

In response to the Committee's findings, JC Scott, President and CEO, the Pharmaceutical Care Management Association (PCMA), underscored how PBMs have stepped up their efforts to help patients with diabetes by introducing new programs to cap or eliminate out-of-pocket costs on insulin. Scott cited a recent industry report that shows PBMs have held net insulin costs flat, and that rising insulin list prices can be blamed on market dominance by a few companies and a lack of alternative generic or biosimilar insulins.

Similarly, effective from January 1 this year, the Centers for Medicare & Medicaid Services (CMS) created the Part D Senior Savings Model demonstration through CMMI that allows beneficiaries to pay static $30 copays for their insulin drugs and avoid the high coverage gap cost sharing responsibilities.

U.S. pharmaceutical industry PhRMA said the Congressional report confirms what the association has been claiming all along, quoting the Committee: "Perverse incentives in the market drove up insulin costs for patients." PhRMA argued that the net prices for the most commonly used classes of insulin have gone down by 40%-50%, on average, since 2014, making insulins less expensive today than in 2017. Further, PhRMA said that the net price of insulin was lowered by 83%, on average, last year, through market dynamics.

The problem is, patients are not sharing in on any of these savings, said PhRMA. The body said the Finance Committee answered its own questions about whether insurers and PBMs have patient interests in mind, as they noted, "PBMs have an incentive for manufacturers to keep list prices high."

PhRMA has suggested the following steps be taken to help patients:

- Share the savings health plans receive from biopharmaceutical companies with patients to lower costs at the pharmacy counter;*
- Allow more patients to access insulin without worrying about deductibles;
- Require that fees for PBMs and other entities in the supply chain are tied to the value of their services, rather than calculated as a percent of medicine prices;
- Modernize the Medicare Part D program by establishing an annual cap on OOP costs and allowing seniors to spread costs throughout the year;
- Provide flat copays for insulin for patients in commercial health plans and those with health insurance through the Affordable Care Act; and

- Count OOP costs paid through third-party discount programs and cost-sharing assistance toward the deductibles and out-of-pocket limits patients face.

*This would alter the Anti-Kickback Statute discount safe harbors in Part D and replace current rebate structures with rebates that would be passed on to point of sale (POS). Sybil Mead, Senior Research Director at EVERSANA, suggested that "The Biden Administration may not be opposed to the spirit of this proposal and may reconsider how to restructure the rebate rules to ensure seniors, rather than PBMs, are benefiting from the rebate negotiations."

Existing Legislation Targeting PBM

While the Biden administration has delayed the implementation of a U.S. Department Health and Human Services' (HHS) November 2020 Final Rule modifying the Anti-Kickback Statute (AKS) discount safe harbor to January 2023, many states have already taken aim at regulating PBM business practices and their potential impact to rising drug costs.

In 2020, EVERSANA Consultants analyzed more than 330 active state healthcare bills and found that approximately one-third of active state legislation actively targets business practices of PBMs, primarily around the issues of:

- Transparency requirements such as reporting requirements for PBMs to disclose information on drug rebates and drug prices
- Laws prohibiting gag clauses for pharmacies
- Policies that target "price spreading"

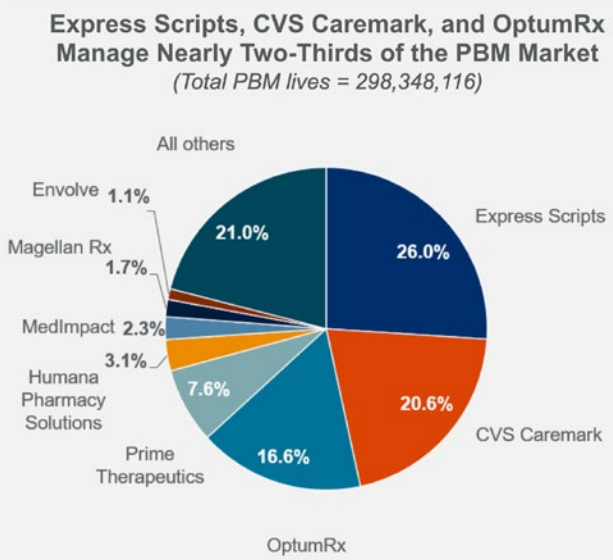
EVERSANA found that five states in particular - Connecticut, Florida, Illinois, Kentucky, and Louisiana - have introduced bills to prohibit the use of copayment accumulator programs. However, only Illinois' bill is still active, as the others ultimately failed to pass. The bills were proposed as a direct tactic to tackle rising drug prices, as copay accumulators are a growing tactic used by PBMs to control drug costs and limit the impact of pharma copayment assistance programs.

The Wider Issue of PBMs

The ultimate goal of the PBM system is to optimize service, value for money and general consumer experience, but as the businesses involved gained power, they began to exploit U.S. citizens in need of prescriptions for their own financial gain.

Prescription drug industry veteran Mesfin Tegenu recently blamed mega-consolidation in the PBM market for rising costs and depriving the industry of innovation, flexibility, quality, and transparency. Even more, net spending on outpatient prescription drugs is forecasted to rise 5% annually from 2020-2028.

He commented, "For all intents and purposes, transparency and competitiveness do not exist in the prescription drug market because of an outdated drug rebate negotiation culture that allows a select few companies to see higher margins and, in turn, dominate the entire prescription drug ecosystem. Rebates were supposed to provide discounts based on quality and control, but now they simply guarantee that a few players receive the greatest economic benefit, effectively locking out competition from regional plans and midsize firms."



Source: Breakaway Partners LLC, Sources of Coverage, April 2019; Health Strategies Insights by EVERSANA, Market Access Macrotrends, February 2020. Note: Express Scripts lives includes Anthem lives which began transitioning to IngenioRx March 2019.

Lisa Idzik, Senior Consultant at EVERSANA, commented, "The three biggest PBMs, Caremark (CVS Health), Express Scripts (Cigna), and OptumRx (United Health Group) have seen the writing on the wall for a while, which obviously is motivating the significant vertical integration moves we have seen over the past few years."

Idzik added that OptumRx in particular is best positioned to move away from rebate structure, if necessary—in fact, it already has made moves to gradually move away from rebates. Beginning in 2020, OptumRx and UnitedHealthcare started to only support new employer clients that incorporated point-of-sale discounts - rebate pass-throughs - to consumers as part of their plan design.

Here to Help

EVERSANA™ is the leading independent provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science services for a healthier world. To learn more about EVERSANA, visit eversana.com.

Zynteglo Roll-out Hit by Double Blow: EU Suspension and NICE Rejection in Past Month

PRICENTRIC BRIEF

- bluebird bio has suspended its roll-out of Zynteglo (betibeglogene autotemcel) pending investigation of a safety concern, according to the European Medicines Agency (EMA), in the same month that the United Kingdom's health technology assessment (HTA) body gave it the cold shoulder for reimbursement on the NHS
- The U.S.-based biotech recently revealed to the EMA that a medicine in its pipeline which uses the same technology as Zynteglo may have been associated with a case of acute myeloid leukemia (AML)
- One week previously, in an appraisal consultation document, the National Institute for Health and Care Excellence (NICE) recommended against the use of the therapy for the treatment of patients with the indication on the grounds that clinical trial data are small and insufficient to justify reimbursement

THE DETAILS

AMSTERDAM, The Netherlands – bluebird bio suspended its roll-out of Zynteglo (betibeglogene autotemcel) pending investigation of a safety concern, according to the European Medicines Agency (EMA), in the same month that the United Kingdom's health technology assessment (HTA) body gave it the cold shoulder for reimbursement on the NHS.

Zynteglo — a gene therapy for the treatment of transfusion-dependent β-thalassemia (TDT) that does not have a β0 / β0 genotype - received a conditional marketing authorization in the EU on 29 May 2019, but its launch has not been as smooth as Bluebird might have hoped.

bluebird Hits Pause in EU

The U.S.-based biotech recently revealed to the EMA that a medicine in its pipeline which uses the same technology as Zynteglo may have been associated with a case of acute myeloid leukemia (AML). Despite the data having no direct links to Zynteglo, the company has halted the marketing of Zynteglo until it can get to the bottom of the suspected safety concern.

The treatment, dubbed "bb1111", uses the same viral vector as Zynteglo, which is based on a type of virus known as a lentivirus.

Cancer caused by insertional oncogenesis had been previously identified as a potential risk of Zynteglo, so patients who have access to the therapy are already monitored post-administration. No cases with Zynteglo have ever been reported, but given the similarity of the mechanism in bb1111, bluebird to put a pause on Zynteglo's sales.

UK Shuns Zynteglo for Reimbursement

One week previously, in an appraisal consultation document, the National Institute for Health and Care Excellence (NICE) recommended against the use of the therapy for the treatment of patients with the indication.

The therapy was rejected on the grounds that clinical trial data are small and insufficient to justify reimbursement, according to NICE, which means that the organization has uncertainties about the cost-effectiveness. Further, the cost-effectiveness estimate for Zynteglo is "considerably" higher than what NICE normally considers an acceptable use of NHS resources at £1,450,000 per patient.

The guidance is not final, as the appraisal committee will meet again to consider the evidence after the opportunity for comments closes on 4 March 2021.

"Living with thalassaemia is a difficult and challenging experience not just for patients but for their entire families," commented Romaine Maharaj, Executive Director, UK Thalassaemia Society.

She continued to say that the organization is "extremely disappointed with NICE's decision not to recommend betibeglogene autotemcel as a treatment option in the UK."

"We also feel disheartened that our patient experts were misquoted and used out of context and feel that NICE needs to rectify this. Having an option and the access to a potentially curable treatment is vital and should be offered to patients."

Nicola Redfern, UK General Manager at bluebird bio, also expressed the company's shock and disappointment at the decision, saying that Bluebird "strongly believe that NICE has failed to act in the best interests of people with TDT and their families in England and Wales."

She continued to say, "It is baffling that NICE disregarded the testimonies of patients, advocacy groups and clinicians and, despite recognizing beti-cel as a potential cure for patients with TDT, has chosen to deny access and has dismissed the obvious unmet need. This decision is deeply concerning and will not only come as a huge blow to the TDT community but also sets a dangerous precedent which could limit access to other gene therapies in the UK in the future."

Alternative Payment Models

Because of the high cost of the treatment, Denmark, Finland, Iceland, Norway, and Sweden have plans to undertake joint negotiations to ensure quick and equal access to the therapy in the Nordics.

The costly therapy has, however, been launched in Germany under a value-based payment agreement with multiple statutory health insurances. The deal means that payers only pay if the therapy delivers on its promise. bluebird's proposed payment model is limited to five payments issued in equal installments: an initial payment at the time of infusion and four additional annual payments if no transfusions for TDT are required for the patient.

The UK has previously adopted alternative payment models in order to get drugs to patients, recently piloting a "subscription-type" payment model with Shionogi's Fetcroja (cefiderocol) and Pfizer's Zavicefta (avibactam). The premise of the model is to move away from paying for individual packs of antimicrobials, instead making annual payments based on health benefits to patients and value to the NHS. It has been dubbed the "Netflix Model" – under which purchasers pay a fixed fee for unlimited patient access to specific products over a set period of time.

Other alternative payment schemes used globally have recently included financial risk-based contracts and health outcomes-based contracts.

EVERSANA Product Manager Magdi Stino noted, "The situation with Zynteglo illustrates the challenges to payers and manufacturers as new curative but ultra-expensive therapies for rare and ultra-rare diseases emerge from the pipeline. Payers seek sufficient clinical evidence, which would not be robustly available for such small populations, as well as certainty on the durability of treatment. Cost-effectiveness is being re-examined in light of these new therapies. Financing of these therapies, especially in risk-sharing agreements and payment terms, continues to grow in importance as new therapies emerge."

NICE Reform

NICE assessed Zynteglo using its Single Technology Assessment process, which is typically used for more standardly priced medicines likely to be used more widely on the NHS, but Nicola Redfern has since insisted that the Highly Specialized Technologies program would have been a more appropriate route, as "The HST committee would have been more familiar with dealing with the uncertainty, with the rare population and with the data set we have."

The rejection is indicative of a bigger picture, and reinforces the ongoing idea that NICE is in need of a working processes upheaval to make way for less traditional drugs.

The UK cost-effectiveness Agency's methodologies when it comes to HTA have long been under scrutiny for remaining broadly unchanged for the past 20 years, despite increasing sophistication of innovative treatments within the modern medicine pipeline.

Despite recognizing the innovative and life-changing gene therapy as a potentially curative treatment, NICE's methods – which have often been criticized for being behind the times when it comes to evaluating non-traditional drugs such as cell and gene therapies – mean that it will not be available to patients who live with the significant burden of TDT.

The group recently, however, sought public feedback on proposals for changes to its methods and processes for developing guidance on medicines, medical devices, and diagnostics.

The organization still uses a cost-effectiveness threshold of £20,000 - £30,000 per quality-adjusted life year (QALY), a number that has not moved since NICE came into being, despite inflation over the last two decades as well as advancements in drug technologies.

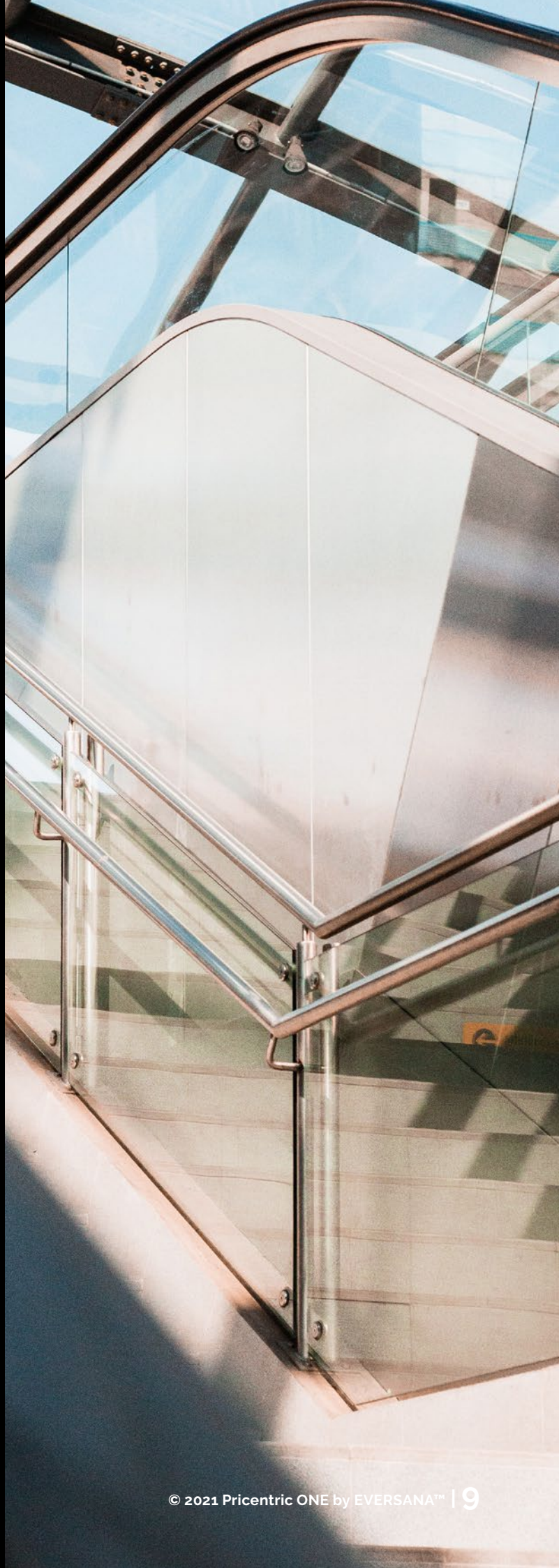
There are exceptions for drugs that meet certain requirements and can be put through Managed Entry Agreements (MAE) or be reimbursed via the aforementioned alternative payment models. However, reformation could potentially help patients gain access to the latest innovative cell and gene therapies like Zynteglo.

Vertex's Kaftrio Plus Kalydeco Offers Considerable Added Benefit, Finds G-BA

Date: February 19, 2021 | Country: GERMANY | Region: EUROPE | Type: HTA |
Keywords: #gba #gkvsv #orphandrug #pricingandreimbursement #vertex

PRICENTRIC BRIEF:

- Germany's Federal Joint Committee (G-BA) has concluded that Vertex's triple-combination therapy Kaftrio (ivacaftor/tezacaftor/elexacaftor) plus Kalydeco (ivacaftor) offers significant benefit versus other therapeutic options, including Vertex's own Symkevi (tezacaftor/ivacaftor), for patients aged 12 years and up with cystic fibrosis (CF) who are either homozygous or heterozygous for the F508del mutation in the CFTR gene
- Professor Josef Hecken, impartial chairperson of G-BA, commented, "The combination therapy with ivacaftor that we have tested can achieve very good results with the patients treated: In the studies, pulmonary exacerbations, i.e. acute worsening of lung symptoms, which often lead to hospital admissions and have an unfavorable effect on the course of the disease, occur significantly less often"
- Within four months of it being on the market, Kaftrio exceeded the EUR 50 million sales threshold for orphan drugs and its status was repealed, ultimately leading to Kaftrio undergoing standard assessment



THE DETAILS

BERLIN, Germany – Germany's Federal Joint Committee (G-BA) has concluded that Vertex's triple-combination therapy Kaftrio (ivacaftor/tezacaftor/elexacaftor) plus Kalydeco (ivacaftor) offers significant benefit versus other therapeutic options for patients with cystic fibrosis (CF).

Kaftrio in combination with Kalydeco was found to offer considerable added benefit in CF patients aged 12 years and up who are homozygous for the F508del mutation in the CFTR gene compared to Symkevi (tezacaftor/ivacaftor) plus Kalydeco, as well as in patients who are heterozygous for the F508del mutation in the CFTR gene and have a minimal function (MF) mutation compared to best supportive care (BSC).

Professor Josef Hecken, impartial chairperson of G-BA, commented, "The combination therapy with ivacaftor that we have tested can achieve very good results with the patients treated: In the studies, pulmonary exacerbations, i.e. acute worsening of lung symptoms, which often lead to hospital admissions and have an unfavorable effect on the course of the disease, occur significantly less often. It is also highly relevant for the patients that we saw advantages in many other patient-reported endpoints and in all measurable aspects of quality of life. For example, in terms of physical well-being, vitality and emotional state."

The rating for Kaftrio with Kalydeco is Germany's highest, the agency noted. Hecken also added, "It is not often that we can certify a significant additional benefit to a drug: This has only been the case three times so far. The special feature of the assessed combination therapy for cystic fibrosis - an orphan drug - is that the result is already based on detailed comparative study data and we have carried out a regular benefit assessment compared to the appropriate comparator therapy."

Vertex submitted a complete dossier to G-BA, despite Kaftrio plus Kalydeco being considered an orphan drug. Within four months of being on the market, Kaftrio exceed the EUR 50 million threshold for sales, meaning its status as an orphan drug was repealed and the drug was subject to standard assessment. Since a full dossier was submitted, G-BA could get right to work.

G-BA's rating will serve as the basis of upcoming pricing negotiations between Germany's umbrella payer GKV-Spitzenverband (GKV-SV) and Vertex, with pricing set to apply starting from September 1, 2021. Of the 8,000 patients with CF in Germany, 2,400 are older than 12 and are expected to benefit from today's decision.

Pricentric INSIGHT: Accurate, Comprehensive and On-Time

Pricentric INSIGHTS delivers accurate, comprehensive insights on major policy and regulatory changes, as well as HTA decisions and drug approvals, in over 100+ markets around the world.

Our team of researchers checks a database of over 700+ reliable sources, including everything from government databases to local newspapers, to provide readers with in-depth updates on the ever-changing pricing and reimbursement landscape.

We also provide conference coverage and utilize our team of consultants to detail how major policy changes can impact market access and the global pricing landscape.

Accurate

Our team verifies every news story and works from a database of validated sources, providing links to the original source where possible.

Comprehensive

Our team provides detailed insights on daily policy and reimbursement updates for products around the globe, covering more than 100 countries to ensure a full overview of every change.

On-time

Our team delivers the news daily and covers trends to encompass the trajectory of policy and regulatory updates, releasing 3000+ articles a year to keep you informed when making company decisions.

Russia Allocates 10B Rubles to Circle of Kindness, SMA Treatments First Area of Focus

Date: February 18, 2021 | Country: RUSSIA | Region: ASIA & SOUTH PACIFIC, EUROPE | Type: Policy | Keywords: #biogen #cellandgenetherapy #circleofkindness #funding #globalaccessscheme #mayozyme #novartis #orphandrug #pediatrics #pompedisease #procurement #raredisease #risdiplam #roche

PRICENTRIC BRIEF:

- Russian Prime Minister Mikhail Mishustin has signed a decree allocating 10 billion rubles for the purchase of medicines for children with rare diseases under the Circle of Kindness Program
- These initial funds are only the first—in total, the federal government has allotted 60 billion rubles for the fund for 2021 so that necessary medicines can be covered for relevant pediatric patients
- The Ministry of Health drew up a list of 30 diseases and 41 medicines to be covered by the program, but to start, the Circle of Kindness is focusing on spinal muscular atrophy (SMA) treatments Biogen's Spinraza (nusinersen), Novartis' Zolgensma (onasemnogene abeparvovec), and Roche's risdiplam, along with Pompe disease treatment Mayozyme

THE DETAILS

MOSCOW, Russia – Russian Prime Minister Mikhail Mishustin has signed a decree allocating 10 billion rubles for the purchase of medicines for children with rare diseases under the Circle of Kindness Program.

These initial funds are only the first—in total, the federal government has allotted 60 billion rubles for the fund for 2021 so that necessary medicines can be covered for relevant pediatric patients.

In January, Russian President Vladimir Putin signed the decree establishing the fund. Putin proposed increasing the income tax rate for citizens who earn more than 5 million rubles a year from 13% to 15% to help fund drugs under the Circle of Kindness. The tax increase, which will create the fund used to cover relevant drugs and diseases, will provide the government with 60 billion rubles in 2021, and this amount will increase per annum.

The Ministry of Health drew up a list of 30 diseases and 41 medicines to be covered by the program. To start, the Circle of Kindness is focusing on spinal muscular atrophy treatments Biogen's Spinraza (nusinersen), Novartis' Zolgensma (onasemnogene abeparvovec), and Roche's risdiplam, along with Pompe disease treatment Mayozyme.

According to Deputy Prime Minister Tatyana Golikova, 466 children out of 890 with SMA in Russia have begun receiving treatment.

As of January, only 23 had been administered Zolgensma, whereas 248 children received Spinraza, with 49 more targeted to begin treatment with Spinraza by the end of the month. The global access program for risdiplam has provided treatment to 187 children on behalf of the company ahead of the planned introduction of risdiplam into civil circulation in May 2021.

Pricentric INSIGHT: How to Determine Price and Global Launch Sequence in a Post-COVID World

Date: February 16, 2021 | Country: UNITED KINGDOM, UNITED STATES | Region: EUROPE, NORTH AMERICA | Type: Drug Launch | Keywords: #brexit #china #covid19 #druglaunch #markets #price #transparency #webinar

PRICENTRIC BRIEF:

- Speaking at a virtual event, Alan Crowther, General Manager Global Pricing, Access and Digital Solutions at EVERSANA and Ed Corbett, Head of EMEA at EVERSANA discussed global pricing and launch sequence changes to come in Europe, the Americas and Asia in 2021
- Specifically, Crowther and Corbett outlined seven major upcoming changes that companies need to take into consideration when planning a launch sequence, such as non-traditional alliances, Brexit, increasing transparency, the EU's pharmaceutical strategy and U.S. reference pricing
- The two discussed concrete actions that companies can take to mitigate issues that this may cause in global product launches

THE DETAILS

PHILADELPHIA, United States & LONDON, United Kingdom – Speaking at a virtual event, Alan Crowther, General Manager Global Pricing, Access and Digital Solutions at EVERSANA and Ed Corbett, Head of EMEA at EVERSANA discussed global pricing and launch sequence changes to come in Europe, the Americas and Asia in 2021.

Specifically, Crowther and Corbett outlined seven major upcoming changes that companies need to take into consideration when planning a launch sequence:

The Rise of Non-traditional Blocs

Various collaborative projects are cropping up globally – The UK recently joined the ACSS, and as such became a part of Project Orbis, the U.S. Food and Drug Administration (FDA)-coordinated collaborative initiative that allows concurrent submission and of promising cancer treatments. According to Ed Corbett, the move signifies the UK's want to distance itself from the European Medicines Agency (EMA), and pursue a potentially more "innovative" approach.

The UK's Departure From the EU

The Medicines and Healthcare Products Regulatory Agency (MHRA) is already trying to prove itself after the UK's recent departure from the EU, having greenlighted various COVID-19 vaccines in substantially quicker timeframes than its counterpart, the EMA. The vaccine regulation is a very "near-term" example of what's to come, noted Corbett, but he expects more prompt approvals in the future, particularly in oncology and rare disease areas.

The Rise of Net Price Transparency

Belgian Secretary of State for Budget and Consumer Affairs Eva De Bleeker recently came under scrutiny for tweeting in a since-deleted tweet the prices for COVID-19 vaccines and the number of doses Belgium intends to purchase. Price transparency is already a hot button issue, especially in European countries like Belgium and Italy, where efforts to disclose prices have been gaining more traction in recent years. For these reasons, Corbett believes that companies need to think carefully about the order in which they launch products in various countries, to make sure that any divulged prices don't destroy value across other markets.

The Prioritization of Launches in Small Markets

Small countries tend to be approving pharmaceuticals faster than larger countries. According to Corbett, this trend demonstrates a race to launch at a global scale that companies need to be aware of. Specifically, Brazil and the UAE are increasingly approving products before full approval has been achieved throughout the EU – one example is Novartis' Piqray (alpelisib), which was approved a full 296 days earlier in the UAE than it was in the EU.

The Rise of China

China is now the second-largest pharmaceutical market in the world after the U.S., and it is becoming an faster launch market. In fact, some big pharma companies have taken to prioritizing China in their launch sequence because of its size - the Chinese market's promise of quantity ultimately makes up

for the offset of the price cuts required to be on the National Reimbursement Drug List (NRDL). Because of this, China is set to displace Europe and Japan as priority markets and is becoming a source of innovation in its own right.

The European Commission's New Pharma Strategy

The European Commission's wide-ranging pharmaceutical strategy is set to be put into action almost immediately, with as many as 30 of its flagship initiatives ready to be implemented within the next year. Corbett noted on the call that due to the fast-moving nature of the new policies, companies would be well placed to take the strategy into account when planning a launch sequence in the future.

U.S. Reference Pricing and "Most-Favored Nation" Rule

The U.S. is undergoing extensive policy changes, some of which were issued by Donald Trump in the final days of his Presidency. The main expected changes are the implementation of external reference pricing leveraging prices found in comparable countries, limiting drug price increases, increased influence of ICER in determining market access and allowing importation of drugs from other countries—in particular, Canada.

What Does This Mean for Launches?

Looking at the various policy and regulation changes being made world-over, Crowther noted that companies need to re-evaluate their product launch sequences to respond to changes at a global level.

The established wave pattern of a product launch is changing, and as such companies need to respond by tweaking and optimizing their own processes and prepare for even more "chaotic adjustments" during the global launch process.

Countries are becoming more grouped based on:

- Speed of launch
- How much IRP impact they have
- Flexibility to launch in a manageable manner to accommodate price risk

As such, Crowther explained that launches are becoming flatter, due to simultaneous entries, as well as more accelerated and riskier due to increasing net price transparency and potential for US reference pricing.

How Can Pharma Prepare?

Both Corbett and Crowther believe that companies should start by challenging internal launch assumptions and plans, and proactively monitoring and reacting to external environments and changes, among other key areas of focus.

To hear the full talk and learn more about how companies can mitigate launch issues, you can listen to the full presentation here.

EVERSANA™ is the leading independent provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science services for a healthier world. To learn more about EVERSANA, visit eversana.com.

Spain's AEMPS Approves Home-Grown CAR-T ARI-0001 for ALL

Country: SPAIN | Region: EU27, EUROPE | Type: Drug Approval | Keywords: #acutelymphoblasticleukemia #aemps #all #ariproject #cartari0001 #carttherapy #cellandgenetherapy #exceptionalauthorization #hematooncology #oncology

PRICENTRIC BRIEF:

- The Spanish Agency for Medicines and Health Products (AEMPS) has approved Hospital Clinic's homegrown CAR-T ARI-0001 as an advanced therapy drug of non-industrial manufacture for the treatment of patients aged 25 years and up with acute lymphoblastic leukemia (ALL) resistant to conventional treatments
- In clinical trials at the Hospital Clinical and Hospital Sant Joan de Deu, CAR-T ARI-0001 was proven to be "safe and very effective, with results comparable to those described for other CAR-T therapies," explained Dr. Alvaro Urbano-Ispizua, Director, Clinical Institute of Hemato-Oncological Diseases
- CAR-T ARI-0001 is the first treatment with genetically modified cells to be granted exceptional authorization in Spain, Spain's first publicly-owned CAR-T, and the first CAR-T therapy developed entirely in Europe to secure approval from a regulatory agency

THE DETAILS

MADRID, Spain – The Spanish Agency for Medicines and Health Products (AEMPS) has approved Hospital Clinic's homegrown CAR-T ARI-0001 as an advanced therapy drug of non-industrial manufacture for the treatment of patients aged 25 years and up with acute lymphoblastic leukemia (ALL) resistant to conventional treatments.

Today's approval is based on results from a clinical trial carried out at the Hospital Clinic and the Hospital Sant Joan de Deu in July 2017 in which CAR-T ARI-0001 produced a complete response in more than 70% of patients. All in all, it was proven that CAR-T ARI-0001 is "safe and very effective, with results comparable to those described for other CAR-T therapies," explained Dr. Alvaro Urbano-Ispizua, Director, Clinical Institute of Hemato-Oncological Diseases.

Since CAR-T ARI-0001 is produced in Spain's hospitals, it can be prepared in "a very short time," further explained Urbano-Ispizua, adding "… we can adapt the treatment according to the characteristics of the patient" and "we can modulate the amount of CARTs to administer or repeat the dose."

CAR-T ARI-0001 Approval - Number of Firsts for Spain

The approval of CAR-T ARI-0001 marks the first treatment with genetically modified cells to be granted exceptional authorization in Spain as part of the country's plan to integrate advanced therapies in the National Health Service (SNS).

Moreover, it's Spain's first publicly-owned and the first CAR-T therapy developed entirely in Europe to secure approval from a regulatory agency.

Regarding the approval of CAR-T ARI-0001, Dr. Cesar Hernandez, Head, AEMPS' Department of Medicines for Human Use, said, "The authorization of use that is granted based on this legislation of advanced therapy medicines of non-industrial manufacture must allow, both the access of patients who do not have other treatment alternatives, and continue generating knowledge about the drug so that, eventually, a centralized marketing authorization for the whole of Europe is obtained."

The ARI Project behind the CAR-T therapy was started by Ari Bende (who passed away from ALL in September 2016) and her mother, Angela Jover beginning with research into improving use of CAR-T therapies and homecare of patients.

Irish Government Releases First EUR 30M for Backlogged Meds, Approves Extension for Funding Agreement

Date: February 9, 2021 | Country: IRELAND | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #backlog #funding #ipha #ireland #medicines #negotiation

PRICENTRIC BRIEF:

- The Irish Government has released the first EUR 30 million of its promised EUR 50 million to help clear a list of "backlogged" medicines, which will help give patients access to treatments for a range of diseases
- In addition to the release of the funding, a new extension to the Agreement has been announced, which will run until the end of July, following an April review
- Last year it was revealed that the Health Service Executive (HSE) of Ireland would not approve any new drugs that generate additional costs for the rest of the year, but the government has now allotted EUR 50 million for the new medicines over the course of the next year

THE DETAILS

DUBLIN, Ireland – The Irish Government has released the first EUR 30 million of its promised EUR 50 million to help clear a list of "backlogged" medicines, which will help give patients access to treatments for a range of diseases, including lung cancer, renal cell carcinoma, urethral carcinoma, leukemia, Parkinson's disease and chronic migraine.

In October, Ireland's Budget announcement allotted EUR 50 million for the new medicines over the course of the next year. Until then the 15 medicines in question were stuck in a backlog for over a year due to a political decision to stop funding new innovative treatments.

This is because last year it was revealed that the Health Service Executive (HSE) of Ireland would not approve any new drugs that generate additional costs for the rest of the year. Instead, HSE would only authorize new drugs that are budget neutral or result in savings being made due to ongoing financial strains on the country's health budget.

In addition to the release of the funding, a new extension to the Agreement has been announced, which will run until the end of July, following an April review.

The extension acts as a "bridge towards negotiating a new Agreement that places the supply and funding of new medicines on a sustainable, predictable footing," according to Oliver O'Connor, Chief Executive of the Irish Pharmaceutical Healthcare Association (IPHA).

He continued, "This extension prepares the ground for a new Agreement, with each side making commitments to the other on joint funding, information-sharing and continuous dialogue. The politicians, especially the Taoiseach and Ministers Donnelly and McGrath, and officials working at the HSE, the Department of Health and the Department of Public Expenditure and Reform deserve significant credit in working together to improve the reimbursement environment.

"We still have some way to go. We want to create a positive context for the Government's decisions for Budget 2022 so that funding for new medicines continues at the right level. Together, we can build towards a resolution that recognizes the shared ambition to give patients the best treatment options at speed and scale."

The Agreement was initially extended in August 2020, and could potentially be extended again if the State decides it needs more time.

Paul Reid, President of IPHA, added: "We have agreed to roll over the extension to the existing Agreement for three reasons. We wanted to give thousands of patients access to the latest treatments by attaching a specific funding amount to medicines we know they need. We wanted to help the State to manage the pandemic by giving them time and space, without the burden of negotiating a new Agreement right now with the industry.

"We wanted to secure the supply of medicines to the health services, especially during Covid, through the governance framework the extension provides. All of this trends towards the start of negotiations on a new supply Agreement during the extension's timeframe. This is an arrangement that works for everyone – for patients, for industry and for the State."

Ireland generally lags the rest of western Europe when it comes to making new medicines available to patients. One of the main impediments to more rapid and widespread access has been limited funding.

PhRMA Report: How Hospital Practices Increase Costs for Employers, Patients

Date: February 9, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy | Keywords: #340bprogram #cms #consolidation #eversana #healthplans #healthstrategiesinsights #hospitals #markups #outpatientsetting #pbms #phrma #prescriptiondrugs #pricetransparency

PRICENTRIC BRIEF:

- The Pharmaceutical Research and Manufacturers of America (PhRMA) has published a new report that "sheds light" on the distribution and pricing of medicines administered in the hospital outpatient setting, an area in which "little information is available," said the bloc
- The report highlights three areas of concern: hospitals markup medicines, making two or three times the amount initially paid for the medicine; hospital consolidation has led to price increases; and hospital profits generated through the 340B program actively incentivize further consolidation and costlier care
- Stephen J. Ubl, President and CEO of PhRMA, commented, "Many actors – including hospitals, insurers and other middlemen – influence what patients pay out of pocket for prescription medicines," adding, "This new report brings transparency to the role hospitals often play in determining the cost of medicines and ultimately what patients pay out of their own pockets"

THE DETAILS

WASHINGTON, D.C., United States – The Pharmaceutical Research and Manufacturers of America (PhRMA) has published a new report that "sheds light" on the distribution and pricing of medicines administered in the hospital outpatient setting, an area in which "little information is available," said the bloc.

Following a previous investigation into the impact of pharmacy middlemen on prescription drug costs at the pharmacy, today's report outlines how hospitals are generating increased profit through markups and consolidation, which result in higher costs for health plans, and, ergo, employers and patients. The report highlights three areas of particular concern.

First, hospitals were found to often inflate the costs of medicines administered to commercially insured patients in outpatient settings, leading to health plans reimbursing hospitals at rates nearly 250% of the amount paid by the hospital for the medicine—meaning, routine markups increase costs that may exceed the net revenue earned by the manufacturer, explained PhRMA.

Second, hospital consolidation was found to cause increased prices, as hospitals used their market power to extract higher payments from commercial health plans, which results in higher costs not only for plans but also for employers and patients.

And third, hospital profits generated through the 340B program were found to be incentivizing consolidation and more costly care. While the 340B program was created by Congress to help increase access to medicines for vulnerable patients, PhRMA said it has since evolved to financially benefit large hospital systems, for-profit pharmacies, and other middlemen.

The problem is, hospitals purchase deeply discounted medicines but then charge higher prices—further, the ability for hospitals to generate a profit has spurred hospitals to bring in even more profit by registering offsite outpatient sites to expand the program. Through this, the number of 340B offsite outpatient sites has jumped to 28,000 in 2020 from 34 in 1994.

PhRMA's Ubl: "Status Quo Isn't Working for Patients"

Stephen J. Ubl, President and CEO of PhRMA, commented, "Many actors – including hospitals, insurers and other middlemen – influence what patients pay out of pocket for prescription medicines. In recent years, nearly half of spending on brand medicines went to someone other than the research companies that developed the medicines. This new report brings transparency to the role hospitals often play in determining the cost of medicines and ultimately what patients pay out of their own pockets."

Ubl added that since the "status quo isn't working for patients," PhRMA is committed to working with policymakers and health care stakeholders to come to a holistic resolution.

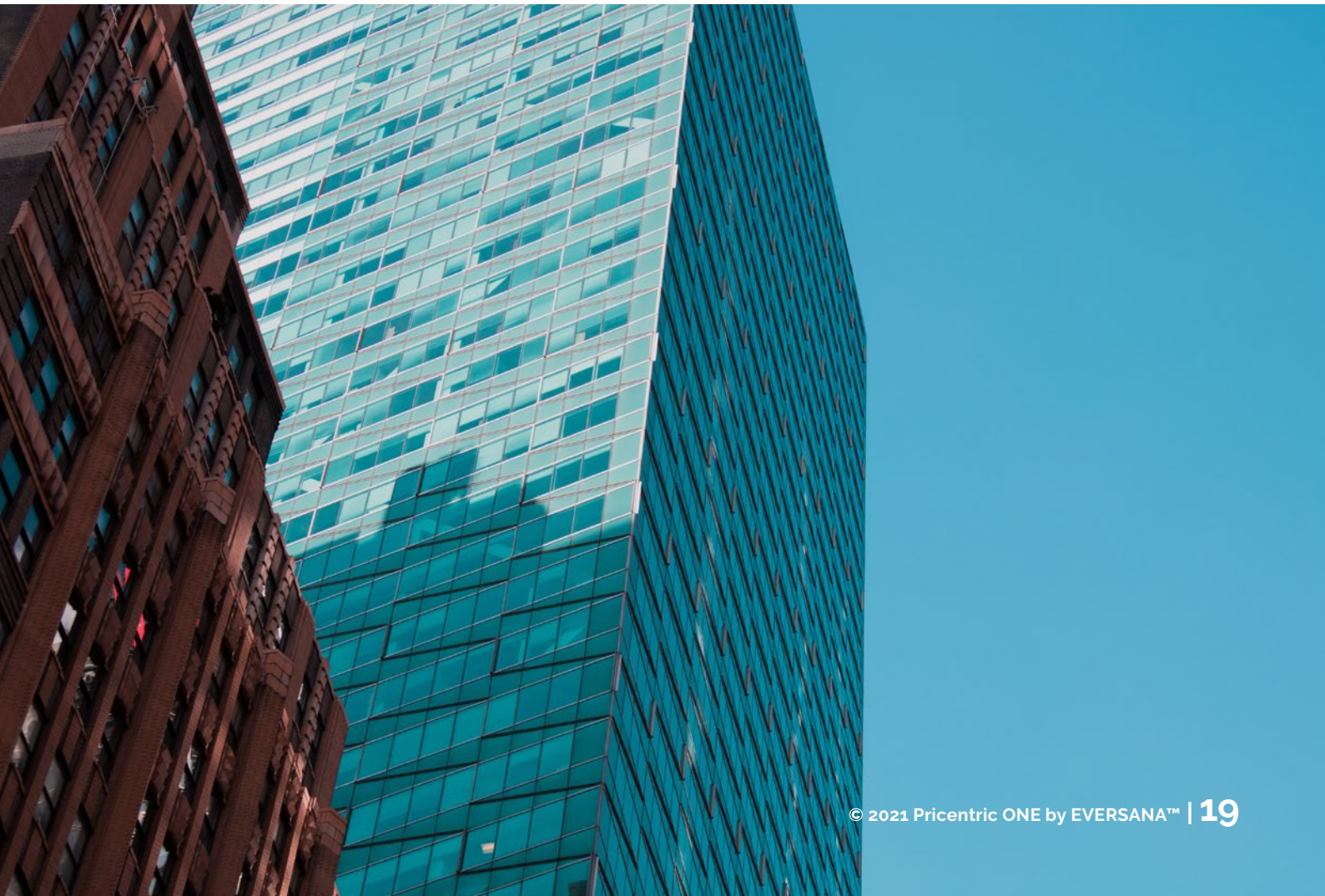
Hospitals, Health Plans, PBMs Facing Greater Regulatory Scrutiny

PhRMA's report comes amidst an environment where hospitals, health plans, and PBMs have been facing slightly greater regulatory scrutiny to business practices that contribute to the rising costs of healthcare, explained Lisa Idzik, Senior Consultant, Market Access Insights, EVERSANA.

At the beginning of this year, the Centers for Medicare and Medicaid Services (CMS) implemented new pricing transparency requirements mandating hospitals to publish on their website a consumer-friendly list of prices for 300 shoppable services. And beginning in 2023, health plans will need to offer an online shopping tool that will allow consumers to see the negotiated rates between their provider and their plan. Concerning 340B, CMS recently finalized a rule that reduces payments for 340B drugs to an Average Sales Price (ASP) minus 22.5%.

Nevertheless, governmental scrutiny of drug pricing will likely remain focused on international reference pricing—however, the direction the new Biden Administration will take is yet to be determined. The "Most-Favored Nations (MFN)" rule introduced by former US President Donald Trump was stalled by the courts, and Biden, shortly after taking office, enacted a 60-day freeze on all Trump's Executive Orders (EOs).

Health Strategies Insights by EVERSANA™ is closely tracking these issues in 2021. Please reach out to HSIclientservices@eversana.com for more information.



G-BA Proposes RWE Scheme for Zolgensma Use in Germany

Date: February 8, 2021 | Country: GERMANY | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #g-ba #hta #monitoring #novartis #pricing #rwd #rwe #sma #zolgensma

PRICENTRIC BRIEF:

- Germany's Federal Joint Committee (G-BA) has asked Novartis to collect data on Zolgensma (onasemnogene abeparvovec) when used in routine clinical practice, in order to evaluate it for an additional benefit assessment
- This is because there is no direct comparison available for Zolgensma, due to the nature and the novelty of the treatment, and as such the G-BA says that its comparison to treatment alternatives cannot yet be conclusively assessed
- In order to mitigate these gaps in data, the G-BA wants Novartis to plan and implement a corresponding registry study in order to close the evidence gaps

THE DETAILS

BERLIN, Germany – Germany's Federal Joint Committee (G-BA) has asked Novartis to collect data on Zolgensma (onasemnogene abeparvovec) when used in routine clinical practice, in order to evaluate it for an additional benefit assessment.

This is because there is no direct comparison available for Zolgensma in the treatment of spinal muscular atrophy (SMA), due to the nature and the novelty of the treatment, and as such the G-BA says that its comparison to treatment alternatives cannot yet be conclusively assessed.

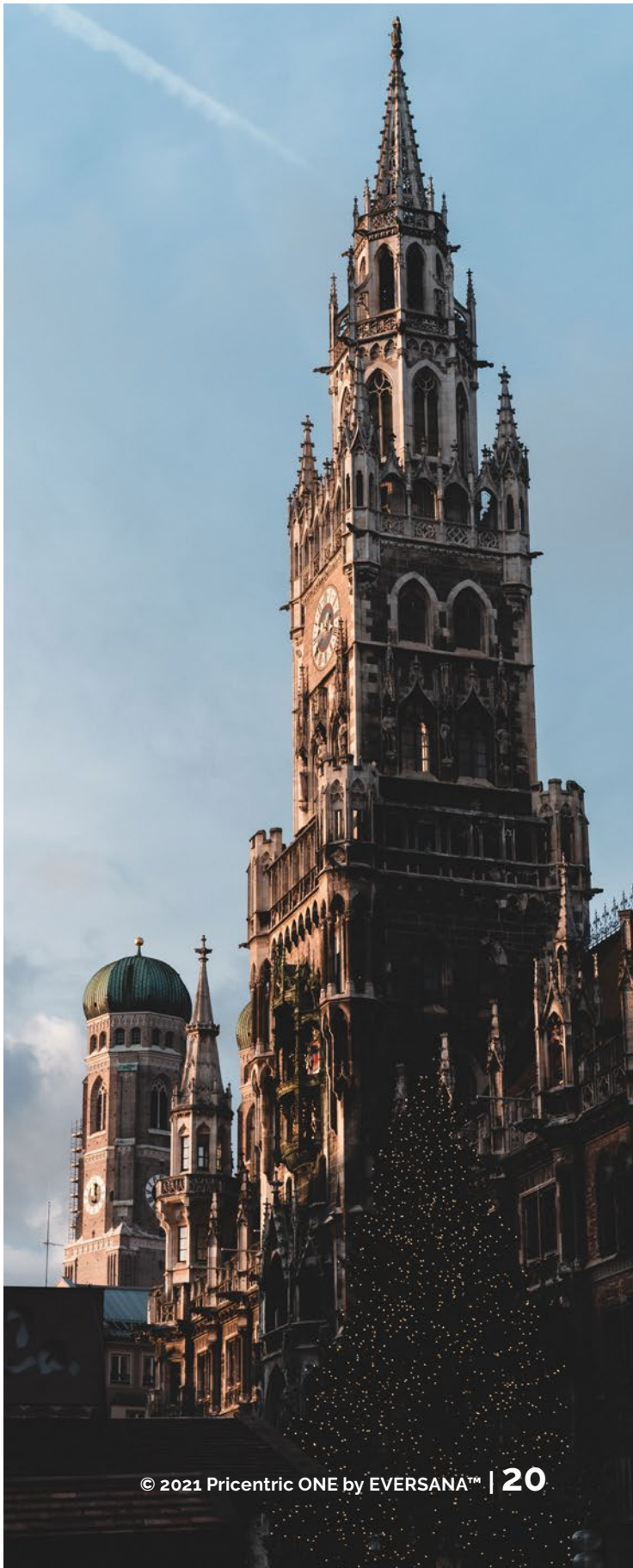
In order to mitigate these gaps in data, the G-BA wants Novartis to plan and implement a corresponding registry study in order to close the evidence gaps.

As such, to help the group form the basis for a new additional benefit assessment, all doctors who want to use Zolgensma are obliged to take part in the data collection.

"We are getting approved drugs with increasingly weaker evidence in the supply. We have to try - especially with drugs for orphan diseases - to keep the balance between the need for urgently needed treatment alternatives and good evidence on the long-term additional benefit of a drug," explained Professor Josef Hecken, impartial chairman of the G-BA.

He continued, "Since a change in the law in 2019, we can now combine the use of the drug with a question we have specified for data collection from supply practice. With the data on the long-term additional benefit obtained from the patients' everyday treatment, the G-BA will be advising again on Zolgensma from summer 2027 at the latest."

The change officially came into effect on February 4, 2021.



China's 4th Round of Volume-Based Procurement Sees 52% Average Price Cuts

Date: February 5, 2021 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: Tender | Keywords: #bidding #cancer #commonlyuseddrugs #diabetes #generics #hospitals #hypertension #pricecuts #smpaa #volumebasedprocurement

PRICENTRIC BRIEF:

- China's fourth round of national centralized volume-based procurement (VBP) of medicines for hospitals and other public medical institutions opened for bidding this week in Shanghai, and Preliminary results, which include the proposed selection of winners, have been posted by the Sunshine Medical Procurement All-in-One Agency (SMPAA)
- Round four sought 45 drugs across a variety of therapeutic areas including hypertension, diabetes, gastrointestinal diseases, mental illnesses, and malignant tumors, and overall, a total of 118 companies out of 152 who participated in the bidding were selected to provide 158 products, at an average reduction in price across the board of 52%
- It is expected that these drugs will be in use after the price reductions negotiated during centralized procurement take effect in May 2021, reported China's state-run news agency Xinhua

THE DETAILS

SHANGHAI, China – China's fourth round of national centralized volume-based procurement (VBP) of medicines for hospitals and other public medical institutions opened for bidding this week in Shanghai.

It is expected that these drugs will be in use after the price reductions negotiated during centralized procurement take effect in May 2021, reported China's state-run news agency Xinhua.

Preliminary results, which include the proposed selection of winners, have been posted by the Sunshine Medical Procurement All-in-One Agency (SMPAA). Further details are set to be published by Monday, but the proposed selected winners can be viewed here. (Pricentric INSIGHTS will issue an updated, translated list when the finalized results become available.)

China's national, centralized procurement has expanded significantly since its pilot known as the "4+7 tender trial" launched in 11 select cities in 2018. On average, China has secured medicines through VBP at price cuts of 53%-54%.

Round four sought 45 drugs across a variety of therapeutic areas including hypertension, diabetes, gastrointestinal diseases, mental illnesses, and malignant tumors. All in all, a total of 118 companies out of 152 who participated in the bidding were selected to provide 158 products, at an average reduction in price across the board of 52%.

As with previous rounds, local manufacturers were successful in winning bids. In round four, a handful of multinational companies—namely, Aurobindo, Eisai, Fresenius Kabi, Sandoz, Sanofi—have so far been reported as winners.

Xinhua detailed that many commonly-used drugs, as well as anti-tumor medicines, will experience significant price reductions as a result of VBP. Esomeprazole enter-coated tablets for gastric ulcers were reported to now have a per tablet price of 3 yuan down from 9 yuan, and bortezomib for the treatment of multiple myeloma, for example, had a price drop from 1,500 yuan to 600 yuan.

Initial analysis of the results has shown that of the 158 products selected, 156 are generic drugs that have passed China's Generic Quality Consistency Evaluation (GQCE). Two products were founded through original research: amisulpride tablets and propofol medium/long-chain fat emulsion injections.

The Chinese Government has always been keen on promoting the capabilities of local drugmakers, especially since production costs are often lower for these companies, so they can offer necessary and widely-used medicines at lower rates. However, this has been a point of contention for foreign drugmakers and a salient criticism of VBP in China because these players must enter their products in the melee at significantly lower prices.

Chinese officials have lauded the program for its "remarkable results," said Han Zheng, Member of the Standing Committee of the Political Bureau of the CPC Central Committee and Vice Premier of the State Council. VBP is set to become an institutionalized practice in China, the scope of drugs up for grabs ever-expanding.

PRICERIGHT®
BY EVERSANA

PriceRight® by EVERSANA

Create Value Across Your Product's Lifecycle

Take control of your pricing strategy across the globe with **PriceRight,** the **first comprehensive software suite** to help you set the optimal price and navigate the complexities of global pricing.

LAUNCH WITH CONFIDENCE.

Use our comprehensive reference-pricing tool to track global pricing by markets, predict revenue trends and easily identify risks and opportunities. Save time and focus your team on what matters by letting our software do the data crunching for you.

MAKE SMARTER DECISIONS.

Our international reference pricing (IRP) simulation software enables you to:

- Enhance your go-to-market strategy and maximize your ROI with our proprietary launch sequence optimization (LSO) algorithm.
- Automatically detect issues that can affect compliance with IRP rules
- Understand risks and forecast impacts of proposed changes on revenue
- Produce presentation-ready graphs and output analyses
- Free up internal resources to focus on other issues

MANAGE TENDERS WITH GREATER CONFIDENCE.

Gain visibility into bids and contract prices in more than 30 countries. Model a full range of discounts with easy-to-set terms and built-in flexibility.

STAY CONNECTED WHEREVER YOU ARE.

Access up-to-date pharmaceutical pricing, price governance proposals and breaking news with the PriceRight mobile app. Customizable notifications and other tools keep you informed and focused on your top priorities.

ACCURATE PRICES.

Monitor prices in over 100 markets and flag when countries are out of compliance.

LAUNCH SEQUENCE.

Our LSO has been used in over 20 major product launches

REFERENCE RULES.

List of all changes to reference rules in over 100 markets.

SECURE.

SOC-2 and ISO 27001 certification.

LEARN MORE AND REQUEST A DEMO AT INFO@EVERSANA.COM

Lombardy's Next Tender: A Big Opportunity for Name-brand & Generic Drugmakers Alike

Date: February 5, 2021 | Country: ITALY | Region: EUROPE | Type: Tender | Keywords: #aria #bidding #consip #eversana #sintelplatform

PRICENTRIC BRIEF:

- Lombardy's state drug-purchaser will soon be announcing another tender for medicines in the region—The previous tender had a value of €5 B and winners were awarded three-year contracts
- The next tender is anticipated to be equally as grand in scope—perhaps even larger than before, given the number of branded medicines whose patents have expired since 2018
- EVERSANA's Director of Tender Solutions Gerardo Peccia says that it's crucial for companies to position products and pricing in the best way to make sure no money is left on the table

THE DETAILS

MILAN, Italy – Lombardy's 100% state-owned drug procurement agency ARIA will soon be announcing a new tender to acquire medicines for the region, and, as with the previous tender, winners will be awarded a three-year contract, with the possibility for extension. The upcoming tender in Lombardy is not only a tremendous opportunity for pharmaceutical companies already established in Italy, but also for generic companies that are aiming to directly penetrate the Italian market.

Ahead of announcing the upcoming tender, ARIA held a roundtable with suppliers. According to Gerardo Peccia, Director, Tender Solutions, EVERSANA, this a notably progressive approach to tendering that underscores the region's commitment to making the rules of play as clear as possible for everyone, in

order to achieve transparent competition and a good outcome for patients.

It's definitely a clever move on Lombardy's part, considering the size of its previous tender. The value was €5,083,132,485.89 for 3,181 lots, including generic products and injectables for oncology, among other medicines—however, biosimilars and vaccines were excluded.

Purchases through ARIA's Sintel Platform began at the end of 2018 and continued until mid-March 2019. As noted by ARIA in a summary of the tender, companies who offered the lowest price for a product were awarded three-year contracts, with the option for a six-month extension. In the end, offers on 2,410 lots of the initial 3,181 were concluded.

Tendering in Italy has always sought reward drugmakers who offer the lowest prices for their products. In national-level tendering directed by CONSIP in September 2020, Italy awarded contracts for biosimilars for many name-brand biologics – in some cases to multiple companies – at a 20% discount compared to the prices of these same medicines charged to public health facilities.

The same holds true for Lombardy's regional tender. In the above example from Lombardy's previous tender, the price of the 1st awarded offer is 47% lower than that of the 2nd for this single lot with a quantity of 96,000 units. Here, the difference between first and second place is noticeably large—first place is nearly half the price of second.

The winning company could have offered almost double the price and still would have won the tender.

In highly-competitive scenarios like the Lombardy tender, significant price cuts often lead to a win, but there is still room to play. Such tenders necessitate price simulation in order to successfully navigate the process and secure a contract with a competitive price.

Lombardy's next tender is scheduled to be announced in June of this year. As such, it can be expected that submissions will start being accepted in July or early August, with purchasing set to commence in June 2022. While the total value and lots of this upcoming tender have yet to be disclosed, both figures should be around the same as the previous round; potentially greater, given the number of medicines whose patents have expired since 2018 and now face generic competition.

"It is, therefore, crucial to position products and pricing in the best way," said Peccia. "An error in the price positioning could have consequences of losing the business (exclusion) or leaving money on the table. They need to avoid bidding too low or too high and shoot themselves in the foot."

Pricentric's Tender Solution is a state-of-the-art tender database with simulation capabilities to help companies strategize for successful bidding, not only in Italy but other markets as well. Given the competitive nature of tendering, especially as more generic products continue to enter the market, planning is crucial for securing a contract that is optimal for both companies and buyers.

EVERSANA™ is the leading independent provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners, and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science services for a healthier world. To learn more about EVERSANA, visit eversana.com.

KPBMA Wants South Korea to be Self-Sufficient, Pharmaceutical Powerhouse

Date: February 3, 2021 | Country: SOUTH KOREA | Region: ASIA & SOUTH PACIFIC | Type: Policy | Keywords: #acquisitions #addedvalue #blockbusterdrugs #domesticproduction #drugsupply #generics #industrialliaisonprogram #innovation #kpbma #mergers #mit #r&d

PRICENTRIC BRIEF:

- The Korean Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) Chair Won Hee-Mok has shared the industry's pledge to nurture South Korea's domestic market, both in terms of blockbuster, innovative medicines and generics, to establish "pharmaceutical sovereignty" post-coronavirus and urged government support, particularly in terms of policy, to make this plan come into fruition
- For South Korea to achieve 50% self-sufficiency in the next five years, KPBMA selected 200 active pharmaceutical ingredients (APIs) out of 2,000 for which localized production is urgent to ensure a stable supply system while promoting domestic manufacturers
- The Association also wants to bring more blockbuster drugs to South Korea through increased research and development (R&D) and expanded mergers and acquisitions, and is setting up shop in Boston to participate in Massachusetts Institute of Technology's (MIT) Industrial Liaison Program (LIP) consortium

THE DETAILS

SEOUL, South Korea – At the new year meeting of the Korean Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA), the association's chair Won Hee-Mok shared the industry's pledge to nurture South Korea's domestic market, both in terms of blockbuster, innovative medicines and generics, to establish "pharmaceutical sovereignty" post-coronavirus.

Ideally, South Korea would achieve 50% self-sufficiency in the next five years by nurturing its domestic drug market. KPBMA selected 200 active pharmaceutical ingredients (APIs) out of 2,000 for which localized production is urgent. Increasing South Korea's self-sufficiency in this area would ensure a stable supply system while promoting domestic manufacturers.

The Association also wants to bring more blockbuster drugs to South Korea through increased research and development (R&D) and expanded mergers and acquisitions. Open innovation requires a focus on advanced medicine, specifically products that create "enormous added value" and offer a range of treatment options for people with rare and intractable diseases.

KPBMA is also setting up shop in the Boston, Massachusetts to participate in Massachusetts Institute of Technology's (MIT) Industrial Liaison Program (ILP) consortium, allowing relevant companies to harness MIT resources to address challenges the industry is facing. The Association is joining the program in collaboration with the UK Life Science Research Institute, noted the KPBMA chair.

These initiatives require government support to come to fruition. During the conference, Won Hee-Mok appealed to government representatives, asking for their help in establishing a "command tower" to foster growth in the industry through policy and support all the way from clinical trials through approval.

Won Hee-Mok said, "I ask you to implement a policy that connects innovation in the pharmaceutical and bioindustry to growth. The bio-health industry is the social safety net that is directly related to public health and growth ... to lead the future national economic power requires a reasonable combination of regulatory policies and development policies."

Pricentric INSIGHT: China Issues New Volume-Based Procurement Policy Document

Date: February 2, 2021 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: Tender | Keywords: #bidding #bmi #centralizedprocurement #generics #gqce #hospital #nrdl #orphandrugs #payment #policy #purchaseagreement #volumebasedprocurement

PRICENTRIC BRIEF:

- China's State Council has published an updated policy document on its centralized volume-based procurement (VBP) scheme entitled "Opinions on Promoting the Normalization and Institutionalization of Centralized Volume-Based Procurement of Drugs" that offers up ways to improve its practice and provides a roadmap for the future of this scheme
- Of note, China seeks to soon procure all drugs with high clinical need, those listed in the NRDL, and potentially orphan drugs through VBP
- All medical institutions are encouraged to participate and prioritize medicines acquired through VBP, and China will prepay 30% of procurement costs to institutions, which will settle directly with drugmakers

THE DETAILS

BEIJING, China – China's State Council has published an updated policy document on its centralized volume-based procurement (VBP) scheme entitled "Opinions on Promoting the Normalization and Institutionalization of Centralized Volume-Based Procurement of Drugs" that offers up ways to improve its practice and provides a roadmap for the future of this scheme.

The recent policy document further solidifies the adoption of this scheme as standard practice for China, clarifying the trajectory of purchases and its continued expansion from the 11-city pilot – dubbed the "4+7 Tender Trial"—inaugurated in 2018.

China wrapped its third round of VBP in December 2020 and soon plans to conclude round four, which targets 41 products by generic name with 90 specifications. With each go, China has expanded the number of drugs up for tendering, these drugs undergoing average price cuts of around 53%-54%.

Increasing Competition, Expanding Tender

Today's document contains 20 measures across seven areas.

VBP will center on National Reimbursement Drug List (NRDL)-listed drugs with large purchase volume and high purchase value. Eventually, all categories of drugs with clinical need and reliable quality will be purchased through the VBP initiative once they meet an undisclosed quantity or amount. China is even looking to establish a similar mechanism for orphan drugs and medicines experiencing supply shortages.

The document specifies that China will engage in neither protective nor discriminatory practices that could lead to favoritism. As always, the generic name will be used and competition among bidders will drive lower prices. Multiple winners will still be allowed, but any price differences resulting from bidding should be fair and reasonable.

Products that have passed consistency evaluation will not be subject to quality grouping. China intends for drugs of different dosages, packaging, and quantities but with the same efficacy and route of administration to be combined to promote competition and is exploring whether different generic drugs with similar indications or functions can be merged.

Quality Generics

Generics that have not been approved in accordance with Generic Quality Consistency Evaluation (GQCE) standards, China's method to clear and boost domestically-produced generics, cannot be included in combined groups of related medicines if there are already three products in that group that have passed GQCE.

For products that have not been cleared by consistency evaluation, China is exploring whether to establish a comprehensive evaluation system for clinical use based on big data—in principle, no more

than two drugs with the same generic name should be grouped.

To further improve VBP, China will verify the base number of drug purchases with medical institution need, figures from previous years, and clinical status. The agreed procurement ratio will be determined according to the purchase amount base and the agreed purchase ratio, with consideration of characteristics of the clinical usage of drugs, market competition, and the number of selected companies who volunteered to participate in the tender. The ratio should be increased to ensure quality and prevent monopolies.

Medical Institution Participation

All medical institutions are encouraged to participate in the national procurement scheme and prioritize the use of medicines acquired this way in hospitals. After all, the proposed number of drugs needed through VBP is based on figures from these institutions.

To encourage greater participation in VBP, China will provide 30% of the costs to purchase these drugs upfront through a special fund, and this prepayment will be deducted from reimbursement requests sent to the Basic Medical Insurance (BMI) scheme.

Payments and Accountability

While the program is expanding nationally, China is still looking for ways for institutions to settle payments directly with drugmakers, potentially through electronic settlement centers. Settlement is based on the prevailing price achieved through VBP, particularly competitive tendering. All products, whether the innovator or the generic, will receive the same payment.

The onus for ensuring funds are properly used further falls under the ambit of medical institutions, which are not only required to prioritize the use of VBP-procured medicines as previously mentioned but also to promote rational drug use to assure budget limitations are not breached. These goals will be checked during routine performance appraisals as part of China's push to improve accountability and quality assurance (QA) measures.

The remaining measures discuss ways to improve the management of VBP, including setting up a regional and national network of procurement mechanisms and task the Shanghai Municipal Pharmaceutical Centralized Bidding and Procurement Affairs Management Office with daily work related to joint-procurement.

COVID-19 Vaccine Highlights

EMA Recommends AZ Vaccine as European Commission Publishes Contract Amid Export Block Row

Date: February 1, 2021 | Country: BELGIUM, UNITED KINGDOM | Region: EU27 + UK, EUROPE | Type: Drug Approval | Keywords: #astrazeneca #commission #covid-19 #european #union #vaccine

PRICENTRIC BRIEF:

- On Friday, the European Commission published its redacted contract with AstraZeneca (AZ) for the company's COVID-19 vaccine, on the same day that the European Medicines Agency (EMA) recommended approval for the UK-grown vaccine
- In a bid to protect its own citizens and mitigate the supply issues, on Friday, the EU also passed a new regulation that introduces export controls on Europe-produced vaccines; including the Pfizer shot produced in Belgium that is a prime part of the UK's vaccinations strategy
- The legislation essentially allows countries in the bloc to deny authorization for vaccine exports if the company making them has not honored existing contracts with the Union

French Company, Valneva, Announces Production of COVID-19 Vaccine Candidate Alongside Ongoing Clinical Studies

Date: February 1, 2021 | Country: FRANCE, UNITED KINGDOM | Region: EUROPE | Type: Regulation | Keywords: #adjuvanted #candidate #covid-19 #inactivated #production #vaccine #valneva

PRICENTRIC BRIEF:

- Valneva SE, a specialty vaccine company focused on the prevention of infectious diseases with a significant unmet medical need, announced it has launched production of its inactivated, adjuvanted COVID-19 vaccine candidate
- Production is taking place alongside ongoing clinical studies in order to speed up the pipeline for the company's vaccine, VLA2001, the only inactivated vaccine candidate in clinical trials against COVID-19 in Europe
- In September 2020, Valneva announced a partnership with the UK government for the supply of up to 190 million doses of its vaccine, starting off with 60 million doses in the second half of 2021 as long as trial results are successful

J&J COVID-19 Vaccine 72% Effective in US, 66% Effective Overall

Date: February 1, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Regulation | Keywords: #covid19 #efficacyresults #j&j #janssen #vaccination #vaccine

PRICENTRIC BRIEF:

- Johnson & Johnson on Friday announced topline efficacy and safety data from the Phase 3 ENSEMBLE clinical trial of its COVID-19 vaccine in development that show it is 66% effective overall in preventing moderate to severe COVID-19 28 days following vaccination
- Onset protection was observed by day 14, and among participants from different geographies, the vaccine showed levels of protection against moderate to severe COVID-19 of 72% in the United States, 66% in Latin America, and 57% in South Africa, 28 days after vaccination
- Further, the vaccine candidate was 85% effective in preventing severe disease across all regions studied, 28 days after vaccination in all adults 18 years and older, and it demonstrated complete protection against COVID-related hospitalization and death also 28 days after vaccination

UK Agrees to 40M Doses of Valneva's COVID-19 Vaccine Candidate

Date: February 2, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Type: Regulation | Keywords: #covid-19 #deal #purchase #vaccine #valneva

PRICENTRIC BRIEF

- On Monday, the UK government inked an agreement to purchase an additional 40 million doses of Valneva's COVID-19 vaccine candidate, bringing the island nation's portfolio to 407 million doses over the course of the next two years
- The deal also strengthens the promise of vaccine production in Scotland in the long term, especially with the government's investment in Valneva's Scottish manufacturing facility that began churning out the vaccine last week
- Valneva's candidate is currently in phase I/II trials and would ultimately require receive regulatory approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA) before it could begin distribution at end of the year

Serum Institute Seeks to Begin Trials for COVID-19 Vaccine Candidate & Launch by June 2021

Date: February 2, 2021 | Country: INDIA | Region: ASIA & SOUTH PACIFIC | Type: Regulation | Keywords: #covid-19 #covishield #institute #launch #serum #trial #vaccine

PRICENTRIC BRIEF:

- Serum Institute of India (SII) has asked to begin trials evaluating another COVID-19 vaccine candidate, Covavax, with plans to launch it by June 2021, the company's CEO Adar Poonawalla announced on Saturday
- The Institute is manufacturing the vaccine in partnership with US-based biotechnology company Novovax— Their partnership was originally announced last year, with the aim of producing 2 billion doses of their COVID-19 vaccine
- Novavax recently announced that its vaccine, NVX-CoV2373, offers an efficacy rate of 89.3% in preventing COVID-19, based on the results of a trial carried out in the UK when the country's new more contagious variant was spreading rapidly

EMA Publishes Safety Update on Comirnaty

Date: February 1, 2021 | Country: BELGIUM, NETHERLANDS | Region: EUROPE | Type: Drug Launch | Keywords: #cma #comirnaty #covid-19 #ema #pfizer

PRICENTRIC BRIEF:

- The European Medicines Agency (EMA) has released its first safety update on a COVID-19 vaccine, issuing an update for Pfizer and BioNTech's Comirnaty
- The document confirms the vaccine's safety profile following data collection and notes that no new side effects were discovered
- The European Commission granted Conditional Marketing Authorization to the shot in December, based on evidence submitted by both companies on a rolling basis, including data from a pivotal Phase 3 clinical study demonstrating a vaccine efficacy rate of 95% in participants with and without prior SARS-CoV-2 infection

GSK, CureVac Join Forces to Develop Next-Gen mRNA COVID-19 Vaccines

Date: February 4, 2021 | Country: GERMANY, UNITED KINGDOM, UNITED STATES | Region: EUROPE, NORTH AMERICA | Type: Regulation | Keywords: #covid19 #curevac #cvncov #glaxosmithkline #manufacture #mrnavaccine #r&d #sarscov2 #vaccine

PRICENTRIC BRIEF:

- GlaxoSmithKline (GSK) and CureVac have announced a new €150m collaboration to jointly develop next-generation mRNA vaccines for COVID-19, the deal including the opportunity for a multi-valent approach to address multiple emerging variants in one vaccine

- Both companies will contribute their resources and know-how to the development of a number of novel mRNA vaccine candidates, multi-valent and monovalent approaches included, to offer broader protection against SARS-CoV2 variants
- The collaboration also builds on CureVac's CVnCoV currently in Phase 2b/3 clinical trial—GSK will support the manufacture of up to 100 million doses of CVnCoV, CureVac's first-generation COVID-19 vaccine candidate, in 2021

Switzerland Increases Moderna Vaccine Order by 6 Million, Requests Additional Data on AZ Shots

Date: February 4, 2021 | Country: SWITZERLAND | Region: EUROPE | Type: Regulation | Keywords: #covid-19 #data #procurement #rolling #switzerland #vaccine

PRICENTRIC BRIEF:

- The Swiss Federal Government has increased its confirmed vaccine order commitment with Moderna from 7.5 million to 13.5 million doses, as Swissmedic asks for more data to be submitted for its rolling evaluation of AstraZeneca's vaccine
- The Federal Government initially ordered 4.5 million doses from Moderna on August 7, 2020, and then another 3 million in December the same year
- AstraZeneca will now have to submit additional efficacy data from a Phase III trial underway in North and South America, which will then be analyzed

Novavax Agrees to Supply Switzerland with COVID-19 Vaccine, as EMA Begins Rolling Review of Shot

Date: February 5, 2021 | Country: BELGIUM, SWITZERLAND, UNITED KINGDOM | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #covid-19 #efficacy #ema #novavax #purchase #switzerland

PRICENTRIC BRIEF:

- Novavax has revealed that Switzerland has secured 6 million doses of its protein-based COVID-19 vaccine candidate, NVX-CoV2373
- Under the binding Heads of Terms deal, Novavax and Switzerland will negotiate a final agreement and the initial delivery of doses for shipping following successful clinical development and regulatory review
- Simultaneously, Novavax announced that the European Medicines Agency's (EMA) human medicines committee (CHMP) has started a rolling review of the vaccine based on preliminary results from non-clinical data

Australia Purchases Extra 10M Doses of Comirnaty

Date: February 5, 2021 | Country: AUSTRALIA | Region: ASIA & SOUTH PACIFIC | Type: Pricing & Reimbursement | Keywords: #australian #biontech #comirnaty #covid-19 #pfizer

PRICENTRIC BRIEF:

- Australia has secured an extra 10 million doses of Pzifer and BioNTech's COVID-19 vaccine, Comirnaty. The additional purchase brings the total number of doses ordered by the country with Pfizer to 20 million
- The additional doses will be available in the second half of 2021, and the vaccine rollout remains on track to begin in late February according to the country's Ministry of Health
- Australia's Therapeutic Goods Administration (TGA) gave the shot the provisional go-ahead in January, but simultaneously warned of national vaccine roll-out issues; AstraZeneca's ongoing global supply issues mean that Australia potentially needs to look at distributing its domestic CSL shot in a shorter timeframe than initially planned

EMA Pilots 'OPEN' Initiative to Share COVID-19 Assessments with Non-EU Regulators

Date: February 5, 2021 | Country: BELGIUM, NETHERLANDS | Region: EUROPE | Type: Policy | Keywords: #commission #covid-19 #european #regulation #transparency #vaccine

PRICENTRIC BRIEF:

- The European Medicines Agency (EMA) has unveiled a new initiative focused on increasing collaboration between European Union (EU) and non-EU drug regulators, ultimately allowing for faster and easier evaluation of COVID-19 vaccines
- The project, dubbed "OPEN", actually started in December 2020, but has only just been made public knowledge
- Australia, Canada, Japan, Switzerland and the World Health Organization (WHO) have been named as the primary participators, under the terms of existing confidentiality arrangements

Novavax COVID-19 Vaccine Rolling Review Begins in U.S., U.K. & Canada

Date: February 8, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Regulation | Keywords: #authorization #covid-19 #fda #healthcanada #mhra #novavax #review #rolling #vaccine

PRICENTRIC BRIEF:

- Novavax announced the start of the rolling review process for authorization of NVX-CoV2373, its COVID-19 vaccine, by multiple regulatory agencies including the European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), U.K. Medicines and Healthcare products Regulatory Agency (MHRA), and Health Canada
- Meanwhile, Novavax will complete its pivotal Phase 3 trials in the United Kingdom and the United States and initial authorization for emergency use granted under country-specific regulations
- NVX-CoV2373 was the first vaccine to demonstrate clinical efficacy against the original strain of COVID-19 and both of the rapidly emerging variants in the United Kingdom and South Africa

South Africa Suspends AZ Vaccine Roll-out as Portugal Joins Germany in Shunning Vaccine for Over 65s

Date: February 8, 2021 | Country: AUSTRIA, FRANCE, GERMANY, NORWAY, PORTUGAL, SOUTH AFRICA | Region: AFRICA, EUROPE | Type: Regulation | Keywords: #astrazeneca #clinical #covid-19 #data #efficacy #rollout #trial #vaccine

PRICENTRIC BRIEF:

- South Africa has suspended the use of AstraZeneca's COVID-19 vaccine following data that shows it offers limited protection against a new strain of the virus
- In a study, the UK-grown shot reduced mild-to-moderate COVID-19 by just 22%, and as such South African Health Minister Zweli Mkhize announced that the region's roll-out program will be put on hold whilst they wait on scientific advice on where to go from here
- AZ has taken a few other hits over the last couple of days, with Portugal also saying that it should preferably be used on only under 65s, joining Germany, France, Austria and Norway, who have all made the same decision

China Approves Inactivated COVID-19 Vaccine by Sinovac

Date: February 9, 2021 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: Drug Approval | Keywords: #beijing #biotechnology #coronavac #covid-19 #inactivated #kexing #sinovac #vaccine #zhongwei

PRICENTRIC BRIEF:

- The National Medical Products Administration (NMPA) has conditionally approved a new COVID-19 inactivated vaccine developed by Beijing Kexing Zhongwei Biotechnology, a part of Sinovac, the company announced over the weekend
- The Sinovac vaccine was approved for emergency use in China last June and has been used for emergency inoculation for certain groups since July last year
- A group of experts from WHO has already arrived in China where they are quarantining and expect to begin inspections next week—The two vaccines developed by Sinovac and Sinopharm have both completed several Phase 3 trials and thus could reach approval by WHO quite swiftly

EU Finalizes Agreement for Extra 300M Pfizer COVID-19 Vaccines

Date: February 10, 2021 | Country: BELGIUM | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #comirnaty #covid-19 #ema #initiative #janssen #johnson #pre #purchase

PRICENTRIC BRIEF:

- The European Commission has purchased 300 million additional doses of the Pfizer/BioNTech COVID-19 vaccine, dubbed "Comirnaty"
- The news comes as the Pfizer jab has been found to be effective against new variants of the virus detected in both South Africa and the United Kingdom
- As it stands, the Commission now has contracts with AstraZeneca (400 million doses), Sanofi-GSK (300 million doses), Johnson and Johnson (400 million doses), BioNTech-Pfizer (600 million doses), CureVac (405 million doses) and Moderna (160 million doses)

FDA Approval for Eli Lilly's COVID-19 Antibody Combo

Date: February 10, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Drug Approval | Keywords: #bamlanivimab #covid-19 #doses #eli #etesevimab #hospitalizations #lilly

PRICENTRIC BRIEF:

- The U.S. Food and Drug Administration has granted emergency use authorization (EUA) to Eli Lilly's COVID-19 combination antibody therapy (bamlanivimab/etesevimab)
- According to the FDA the decision was data released on Jan 26, which showed that when used in combination, bamlanivimab 2800 mg and etesevimab 2800 mg actually reduced COVID-19-related hospitalizations and deaths by as much as 70%
- As of the decision, the treatment will now be available to patients immediately as "There are 100,000 doses ready immediately and an additional 150,000 doses will be available throughout the first quarter," according to the Company

WHO Backs AZ Vaccine Amid Concerns, Supports Longer Dosing Schedule

Date: February 11, 2021 | Country: BELGIUM, NETHERLANDS, SWITZERLAND, UNITED STATES | Region: EUROPE | Type: Policy | Keywords: #africa #astrazeneca #coronavirus

PRICENTRIC BRIEF:

- The World Health Organization (WHO) has recommended wide use of the AstraZeneca (AZ) and Oxford University COVID-19 vaccine in adults over 18, regardless of variant situation
- The decision, which was made by WHO's Strategic Advisory Group of Experts on Immunisation (SAGE) panel, comes just after South Africa suspended the use of AstraZeneca's

COVID-19 vaccine following data that shows it offers limited protection against a new strain of the virus

- In addition to the backing, WHO declared that the dosing schedule should be an interval of eight to 12 weeks, which is in keeping with the UK's roll-out scheme

Pakistan to Exempt Imported Vaccines from Price Caps

Date: February 12, 2021 | Country: PAKISTAN | Region: ASIA & SOUTH PACIFIC | Type: Regulation | Keywords: #astrazeneca #cansinobiologics #covid19 #maximumprices #nationalhealthservice #pricecaps

PRICENTRIC BRIEF:

- Reuters has reported that Pakistan intends to allow private companies to important vaccines against COVID-19 and will exempt these imports from price caps
- According to documents reviewed by Reuters, the National Health Services, Regulations, and Coordination divisions have pursued a special cabinet exemption to allow these imports and exclude them from price caps typically applied to all drug sales in Pakistan
- So far, Pakistan has approved COVID-19 vaccines from China's SinoPharm, AstraZeneca, and, most recently, Russia (Sputnik V), and is working to close a deal for "tens of millions" of vaccine doses from China's CanSino Biologics

U.S. Finalizes 200M Extra Pfizer Vaccine Doses

Date: February 15, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Pricing & Reimbursement | Keywords: #comirnaty #doses #moderna #pfizer #states #united #vaccine

PRICENTRIC BRIEF:

- The U.S. government has exercised its pre-existing option for an additional 100 million doses of Pfizer-BioNTech's COVID-19 vaccine, bringing the total number of doses to be supplied to 300 million
- Under the agreement, the U.S. will pay $1.95 billion for the additional doses to make the newly acquired doses available in May
- The move comes as Biden noted last Thursday that there will not be enough coronavirus vaccine doses to vaccinate all Americans by the end of the summer

Japan Opens Gate for Pfizer's COVID-19 Vaccine

Date: February 16, 2021 | Country: JAPAN | Region: ASIA & SOUTH PACIFIC | Type: Drug Approval | Keywords: #covid-19 #mhlw #pfizer #vaccine

PRICENTRIC BRIEF:

- The Ministry of Health, Labor and Welfare (MHLW) has approved Pfizer's vaccine against COVID-19 for people aged 16 or older
- On the same day, a batch of approximately 400,000 doses was shipped from Belgium to Japan, with vaccinations planned to begin on Wednesday at a medical facility in Tokyo before spreading to other locations
- Public skepticism in Japan, however, could stand in the way of herd immunity, as well as new restrictions on exports from the European Union creating uncertainty about the timing and size of further shipments

Canada Orders 4M More Doses of Moderna's COVID-19 Vaccine, Totaling Commitment to 44M Doses

Date: February 16, 2021 | Country: CANADA-ONTARIO | Region: NORTH AMERICA | Type: Drug Approval | Keywords: #covid-19 #moderna #vaccine

PRICENTRIC BRIEF:

- The Canadian Government has expanded its confirmed order commitment of Moderna's COVID-19 Vaccine by 4 million doses, meaning the country is now committed to a total of 44 million doses
- "Today's increased supply agreement from the Canadian government reaffirms the confidence in Moderna's COVID-19 vaccine," said Stephane Bancel, Chief Executive Officer of Moderna

- On December 23, Health Canada authorized the vaccine for the immunization of people 18 years of age and older, emphasizing that the less restrictive storage and handling requirements of Moderna's vaccine enable it to be distributed to remote communities

Australia Gives Provisional Approval to AstraZeneca COVID-19 Vaccine

Date: February 17, 2021 | Country: AUSTRALIA | Region: ASIA & SOUTH PACIFIC | Type: Drug Approval | Keywords: #astrazeneca #az #covid-19 #provisional #tga #vaccine

PRICENTRIC BRIEF:

- The Therapeutic Goods Administration (TGA) has granted provisional approval to AstraZeneca for its COVID-19 vaccine
- The product is the second COVID-19 vaccine to thus far receive Australian regulatory approval after the vaccine developed by Pfizer and BioNTech
- While data show that AstraZeneca's vaccine prevents COVID-19, it is unclear whether it prevents transmission or asymptomatic disease—AstraZeneca is required to continue submitting to the TGA longer term efficacy and safety data

WHO Grants Emergency Use Authorization for AZ COVID-19 Vaccine

Date: February 17, 2021 | Region: AFRICA, ASIA & SOUTH PACIFIC, EUROPE, MIDDLE EAST, NORTH AMERICA, SOUTH AMERICA | Type: Drug Approval | Keywords: #astrazeneca #emergencyuselisting #health #organization #who #world

PRICENTRIC BRIEF:

- The World Health Organization (WHO) has given Emergency Use Listing to AstraZeneca for its COVID-19 vaccine, in a move that paves the way for the jab to be used globally
- The WHO listing specifically applies to the Serum Institute of India and AstraZeneca-SKBio of Korea-produced shares of the vaccine, which will be used for administration in low- and middle-income countries
- The approval means that countries can expedite their own approval processes, meaning that "Countries with no access to vaccines to date will finally be able to start vaccinating their health workers and populations at risk, contributing to the COVAX Facility's goal of equitable vaccine distribution," explained Dr Mariângela Simão, WHO Assistant-Director General for Access to Medicines and Health Products

EC Secures More Moderna, Pfizer Vaccine Doses

Date: February 18, 2021 | Country: BELGIUM | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #approved #comirnaty #contract #doses #moderna #pfizer #vaccine

PRICENTRIC BRIEF:

- The European Commission has approved a second contract with Moderna to ensure up to an additional 300 million doses of its COVID-19 vaccine, and another contract with Pfizer and BioNTech for 200 million doses of its vaccine Comirnaty
- The Moderna contract entitles the Commission to 150 million doses in 2021 and an option to purchase an additional 150 million in 2022, which will then be available to all EU Member States
- The Pfizer deal adds an additional 200 million doses to the already-confirmed 300 million that were agreed last year between the company and the Commission, bringing the total amount of ordered shots to 500 million, with the potential to increase to 600 million based on the option granted in the new agreement

EMA Publishes Full Overview of AZ Vaccine

Date: February 19, 2021 | Country: BELGIUM, NETHERLANDS | Region: EUROPE | Type: Drug Approval | Keywords: #agency #astrazeneca #commission #covid19 #european #medicines #vaccine

PRICENTRIC BRIEF:

- The European Medicines Agency (EMA) has published a full overview of AstraZeneca's COVID-19 vaccine, following its recommendation at the end of January

- The overview clarifies that the vaccine offers a "good level of protection" against the virus, and notes that the Agency believes the benefits are greater than the risks, and as such the shot can be authorized for use in the EU
- On January 29, the EMA recommended granting a conditional marketing authorization for the vaccine, making it the third COVID-19 vaccination to be approved in the EU

Dr. Reddy's Kicks Off EUA Process for Sputnik V in India

Date: February 22, 2021 | Country: INDIA | Region: ASIA & SOUTH PACIFIC | Type: Regulation | Keywords: #covid19 #drreddys #drugscontrollergeneralofindia #emergencyuseauthorization #russiandirectinvestmentfund #sputnikv #vaccine

PRICENTRIC BRIEF:

- Dr. Reddy's Labs has commenced the Emergency Use Authorization (EUA) process with the Drugs Controller General of India (DCGI) for COVID-19 vaccine candidate Sputnik V
- Dr. Reddy's will be presenting the safety profile of the Phase 2 study and interim data from the Phase 3 study of Sputnik V, which has been ongoing in India but was expected to wrap this past weekend
- The company partnered with the Russian Direct Investment Fund (RDIF) to conduct clinical trials of Sputnik V and has secured distribution rights for the vaccine in India

European Commission Launches 'HERA Incubator' to Tackle New COVID-19 Variants

Date: February 22, 2021 | Country: BELGIUM | Region: EUROPE | Type: Policy | Keywords: #commission #covid19 #european #pandemic #vaccine #variant

PRICENTRIC BRIEF:

- On 17 February, the Commission presented its new "HERA Incubator", a European bio-defense preparedness plan against potential COVID-19 variants
- The project will combine the expertise of researchers, biotech companies, manufacturers and public authorities in the European Union and globally, in order to detect any new variants and get a head start on adapting and evolving vaccines in response
- One the pandemic is no longer at the forefront of the Commission's priorities, the HERA Incubator will serve as a blueprint for the EU's long-term preparedness for health emergencies

Novavax Agrees to Provide 1.1B COVID-19 Vaccines to COVAX

Date: February 22, 2021 | Country: SWITZERLAND | Region: EUROPE | Type: Regulation | Keywords: #covid19 #gavi #mou #novavax #procurement #vaccine

PRICENTRIC BRIEF:

- Novavax has signed a Memorandum of Understanding (MOU) with GAVI to provide 1.1 billion doses of its COVID-19 vaccine, NVX-CoV2373, to the COVAX initiative
- According to GAVI, the doses will be made available to the Facility via both a final advance purchase agreement with Novavax, once signed, and an existing agreement between GAVI and the Serum Institute of India (SII)
- The Novavax shot was the first vaccine to demonstrate clinical efficacy against the original strain of COVID-19 and both of the rapidly emerging variants in the United Kingdom and South Africa

COVID-19 Vaccine Tracker

Company	Vaccine	Technology	Trial Phase	Efficacy	U.S. Deals
Moderna & National Institutes of Health	mRNA-1273	mRNA	3	94.5%	300 million doses
Pfizer & BioNTech	Comirnaty (BNT162b2)	mRNA	Combined 2 and 3	95%	300 million doses
CureVac	CVnCoV	mRNA	3	unknown	-
CanSino Biologics & Military	Convidecia (Ad5-nCoV)	Viral vector	3	65.7%	-
J & J & Beth Israel	Ad26.COV2.S	Viral vector	3	72%	$1 billion / 100 million doses
Gamaleya Research Institute	Sputnik V (Gam-Covid-Vac)	Viral vector	3	91.6%	-
AstraZeneca & U Oxford	AZD1222	Viral vector	Combined 2 and 3	82.4%	$1.2 billion / 300 million doses
Novavax	NVX-CoV2373	Protein-based	3	89.3%	$1.6 billion / 110 million doses
Medicago & GSK	CoVLP	Protein-based	Combined 2 and 3	Unknown	-
Sanofi & GSK	-	Protein-based	2	Unknown	$2.1 million /100 million doses
Wuhan Institute & Sinopharm	BBIBP-CorV	Attenuated coronavirus	3	79.34%	-
Sinovac	CoronaVac	Attenuated coronavirus	3	50.38%	-

Efficacy rates and U.S. deals were sourced from The New York Times.

HTAs, Approvals, Launches & Price Changes

HTA Decisions: France

- HAS/TC in France has conducted an assessment of Praluent (Alirocumab; Sanofi) for Prevention Of Cardiovascular Complications. Result: In primary hypercholesterolemia and mixed dyslipidemia, the actual benefit is insufficient to justify its coverage by national solidarity in other populations in the marketing authorization. The actual benefit is insufficient to justify coverage by national solidarity in other populations of the indication "established atherosclerotic cardiovascular disease", including PRALUENT (alirocumab) as monotherapy or in combination with other lipid-lowering therapies at: 1. Statin-intolerant patients or in whom statins are contraindicated, or 2. Patients with established atherosclerotic cardiovascular disease other than a history of recent ACS, or 3. Patients who do not have associated hypercholesterolemia, or patients not receiving optimized treatment with at least one statin at the maximum tolerated dose.
- HAS/TC in France has conducted an assessment of Verzenios (Abemaciclib; Eli Lilly) for Breast Cancer (er+) (fulvestrant). Result: The actual benefit of VERZENIOS (abemaciclib) remains substantial in combination with fulvestrant in postmenopausal women with locally advanced or metastatic RH+/HER2- breast cancer, without symptomatic visceral involvement threatening life in the short term, first-line metastatic in women with early relapse of adjuvant hormone therapy as well as in the second metastatic line after a first-line of hormone therapy.
- HAS/TC in France has conducted an assessment of Olumiant (Baricitinib; Eli Lilly) for Atopic Dermatitis. Result: The actual benefit of OLUMIANT 2 mg and 4 mg (baricitinib) film-coated tablets is low in the treatment of moderate to severe atopic dermatitis in adults which requires systemic treatment only in the event of failure, intolerance, contraindication to ciclosporin.
- HAS/TC in France has conducted an assessment of Olumiant (Baricitinib; Eli Lilly) for Atopic Dermatitis. Result: The actual benefit of OLUMIANT 2 mg and 4 mg (baricitinib), film-coated tablets, is insufficient to justify coverage by national solidarity about the alternatives available in patients who have failed topical and naive treatments due to lack of comparative data.
- HAS/TC in France has conducted an assessment of Praluent (Alirocumab; Sanofi) for Prevention Of Cardiovascular Complications. Result: In primary hypercholesterolemia and mixed dyslipidemia, the actual benefit is insufficient to justify its coverage by national solidarity in other populations in the marketing authorization. The actual benefit is insufficient to justify coverage by national solidarity in other populations of the indication "established atherosclerotic cardiovascular disease", including PRALUENT (alirocumab) as monotherapy or in combination with other lipid-lowering therapies at: 1. Statin-intolerant patients or in whom statins are contraindicated, or 2. Patients with established atherosclerotic cardiovascular disease other than a history of recent ACS, or 3. Patients who do not have associated hypercholesterolemia, or patients not receiving optimized treatment with at least one statin at the maximum tolerated dose.
- HAS/TC in France has conducted an assessment of Praluent (Alirocumab; Sanofi) for Hypercholesterolemia. Result: In primary hypercholesterolemia and mixed dyslipidemia, the actual benefit is insufficient to justify its coverage by national solidarity in other populations in the marketing authorization. The actual benefit is insufficient to justify coverage by national solidarity in other populations of the indication "established atherosclerotic cardiovascular disease", including PRALUENT (alirocumab) as monotherapy or in combination with other lipid-lowering therapies at: 1. Statin-intolerant patients or in whom statins are contraindicated, or 2. Patients with established atherosclerotic cardiovascular disease other than a history of recent ACS, or 3. Patients who do not have associated hypercholesterolemia, or patients not receiving optimized treatment with at least one statin at the maximum tolerated dose.

HTA Decisions: France (cont.)

- HAS/TC in France has conducted an assessment of Praluent (Alirocumab; Sanofi) for Prevention Of Cardiovascular Complications. Result: In primary hypercholesterolemia and mixed dyslipidemia, the actual benefit of PRALUENT 300 mg (alirocumab) is substantial in combination with optimized lipid-lowering treatment in adult patients with heterozygous familial hypercholesterolemia, which is insufficiently controlled and requiring treatment with LDL-apheresis. In the indication "established atherosclerotic cardiovascular disease", the actual benefit of PRALUENT 300 mg (alirocumab) is significant only in combination with optimized lipid-lowering treatment in adult patients with atherosclerotic cardiovascular disease established by a history of recent ACS (prevention secondary) and which are not controlled (LDL-c = 0.7 g / L) despite an optimized lipid-lowering treatment comprising at least one statin at the maximum tolerated dose.

- HAS/TC in France has conducted an assessment of Praluent (Alirocumab; Sanofi) for Hypercholesterolemia. Result: In primary hypercholesterolemia and mixed dyslipidemia, the actual benefit of PRALUENT 300 mg (alirocumab) is substantial in combination with optimized lipid-lowering treatment in adult patients with heterozygous familial hypercholesterolemia, which is insufficiently controlled and requiring treatment with LDL-apheresis. In the indication "established atherosclerotic cardiovascular disease", the actual benefit of PRALUENT 300 mg (alirocumab) is significant only in combination with optimized lipid-lowering treatment in adult patients with atherosclerotic cardiovascular disease established by a history of recent ACS (prevention secondary) and which are not controlled (LDL-c = 0.7 g / L) despite an optimized lipid-lowering treatment comprising at least one statin at the maximum tolerated dose.

HTA Decisions: United Kingdom

- NICE in United Kingdom has conducted an assessment of Beovu (Brolucizumab; Novartis) for Amd. Result: Brolucizumab is recommended as an option for treating wet age-related macular degeneration in adults, only if, in the eye to be treated: 1. The best-corrected visual acuity is between 6/12 and 6/96 2. There is no permanent structural damage to the central fovea 3. The lesion size is less than or equal to 12 disc areas in greatest linear dimension and 4. There is recent presumed disease progression (for example, blood vessel growth, as shown by fluorescein angiography, or recent visual acuity changes). It is recommended only if the company provides brolucizumab according to the commercial arrangement.

- NICE in United Kingdom has conducted an assessment of Nucala (Mepolizumab; Glaxosmithkline) for Asthma (eosinophilic). Result: Mepolizumab, as add-on therapy, is recommended as an option for treating severe refractory eosinophilic asthma, only if it's used for adults who have agreed to follow the optimized standard treatment plan and the blood eosinophil count has been recorded as 300 cells per microliter or more, and the person has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months or has had continuous oral corticosteroids of at least the equivalent of prednisolone 5 mg per day over the previous 6 months or the blood eosinophil count have been recorded as 400 cells per microliter or more and the person has had at least 3 exacerbations needing systemic corticosteroids in the previous 12 months (so they are also eligible for either benralizumab or reslizumab). Mepolizumab is recommended only if the company provides it according to the commercial arrangement.

HTA Decisions: UK (cont.)

- NICE in United Kingdom has conducted an assessment of Nucala (Mepolizumab; Glaxosmithkline) for Asthma (eosinophilic). Result: Mepolizumab, as add-on therapy, is recommended as an option for treating severe refractory eosinophilic asthma, only if it's used for adults who have agreed to follow the optimized standard treatment plan and the blood eosinophil count has been recorded as 300 cells per microliter or more, and the person has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months or has had continuous oral corticosteroids of at least the equivalent of prednisolone 5 mg per day over the previous 6 months or the blood eosinophil count have been recorded as 400 cells per microliter or more and the person has had at least 3 exacerbations needing systemic corticosteroids in the previous 12 months (so they are also eligible for either benralizumab or reslizumab). Mepolizumab is recommended only if the company provides it according to the commercial arrangement.

HTA Decisions: Germany

- G-BA in Germany has conducted an assessment of Ofev (Nintedanib; Boehringer Ingelheim) for Systemic Sclerosis-associated Interstitial Lung Disease. Result: Given the positive approval decision and considering the available data, the G-BA concludes that the identified disadvantages of nintedanib + BSC compared to placebo + BSC do not lead to the derivation of a lesser benefit. In the overall assessment, the G-BA, therefore, concluded that an additional benefit of nintedanib over BSC for the treatment of adult patients with SSc-ILD has not been proven.
- G-BA in Germany has conducted an assessment of Enerzair Breezhaler (Glycopyrronium Bromide + Mometasone + Indacaterol; Novartis) for Asthma. Result: For the benefit assessment of the active ingredient combination indacaterol acetate/glycopyrronium bromide/mometasone furoate for the treatment of adult patients with asthma who are not adequately controlled with a combination of a LABA and a high dose of an inhaled corticosteroid as maintenance therapy and who have had one or more asthma exacerbations in the previous year results from the randomized, controlled Phase III study ARGON on mortality, morbidity, health-related quality of life, and side effects compared to treatment with salmeterol /fluticasone and tiotropium are available. There were no significant differences between the treatment groups in any outcome category. Therefore, additional benefit not proven.
- G-BA in Germany has conducted an assessment of Ofev (Nintedanib; Boehringer Ingelheim) for Chronic Fibrosing Interstitial Lung Diseases. Result: The INBUILD study produced results on mortality, morbidity, and side effects. In the morbidity category, a statistically significant advantage of nintedanib + BSC over placebo + BSC was determined for the combined endpoint acute exacerbation or death. After considering the available data, the G-BA concluded that there was a minor additional benefit of nintedanib compared to BSC for the treatment of adult patients with chronic PF-ILD.
- G-BA in Germany has conducted an assessment of Selgamis (Trifarotene; Galderma) for Acne. Result: Due to a lack of comparison with the ACT, both the placebo-controlled studies PERFECT-1 and PERFECT-2 and the one-arm study SATISFY are unsuitable for the benefit assessment according to section 35a of the book V of the social code. An additional benefit of trifaroten compared to the ACT is therefore not occupied.

PRICENTRIC ONE
BY EVERSANA™

Did you know Pricentric can help you with...

Monthly Reporting

Pricentric can help with custom monthly reporting based on you exact requirements and templates.

Source Validation

Source proofs / screen shots for regulatory reporting.

In a Hurry

Out of time, no problem. The Pricentric Support Team can pull the data for you.
Just send over your request and we will turn it around in a flash.

Launch Monitoring

Live monitoring is now available within the Pricentric portal with email and in-app notifications.
Pricentric can help you track important launches in real-time with precision.

Data Integration

Pricentric can be easily integrated into internal systems via the Pricentric Web API, XML, JSON, or custom formats. Pricentric integrates with the PriceRight Unity Suite (Price Governance / IPR / Launch Sequencing, Tender Management) in real-time!

Ready to get started?

Just message us on Live Chat or email: pricentric@eversana.com.

Note, these services are free and included as part of your Pricentric INSIGHTS Subscription.

HTA Decisions: Germany (cont.)

- IQWiG in Germany has conducted an assessment of Olumiant (Baricitinib; Eli Lilly) for Atopic Dermatitis. Result: The company provided no data for the assessment of the added benefit of baricitinib over the ACT in the treatment of adult patients with moderate to severe atopic dermatitis for whom systemic therapy is an option and for whom long-term/continuous systemic therapy is not indicated. So, there is no hint of an added benefit of baricitinib compared to the ACT; hence, an added benefit remains unproven.
- IQWiG in Germany has conducted an assessment of Olumiant (Baricitinib; Eli Lilly) for Atopic Dermatitis. Result: No suitable data is available for the added benefit of baricitinib over the ACT in the treatment of adult patients with moderate to severe atopic dermatitis for which systemic therapy is possible and for which permanent/ continuous systemic therapy is indicated. Therefore added benefit is not proven.

Drug Approvals: United States

- POSIMIR (BUPIVACAINE) was approved by the FDA in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression. Limitations of Use Safety and effectiveness have not been established in other surgical procedures, including soft tissue surgical procedures, other orthopedic procedures, including for intra-articular administration, and boney procedures, or when used for neuraxial or peripheral nerve blockade.
  Company: DURECT
- TEPMETKO (TEPOTINIB HYDROCHLORIDE) was approved by the FDA for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymalepithelial transition (MET) exon 14 skipping alterations.
  Company: EMD SERONO
- UKONIQ (UMBRALISIB) was approved by the FDA for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL), follicular lymphoma (FL).
  Company: RHIZEN
- BREYANZI (LISOCABTAGENE MARALEUCEL) was approved by the FDA for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.
  Company: JUNO THERAPEUTICS
- LIBTAYO (CEMIPLIMAB-RWLC) was approved by the FDA for patients with locally advanced basal cell carcinoma (laBCC) previously treated with a hedgehog pathway inhibitor (HHI) and for whom a HHI is inappropriate. It was also granted accelerated approval to cemiplimab-rwlc for patients with metastatic BCC (mBCC) previously treated with a HHI and for whom a HHI is inappropriate.
  Company: REGENERON

Drug Approvals: United States (cont.)

- EVKEEZA (EVINACUMAB-DGNB) was approved by the FDA to treat adult and pediatric patients aged 12 years and older with homozygous familial hypercholesterolemia (HoFH).
  Company: REGENERON
- COSELA (TRILACICLIB) was approved by the FDA to reduce the frequency of chemotherapy-induced bone marrow suppression in adults receiving certain types of chemotherapy for extensive-stage (when the cancer has spread beyond the lungs) small cell lung cancer.
  Company: G1 THERAPEUTICS
- ACETAMINOPHEN (ACETAMINOPHEN) was approved by the FDA for the 1. Management of mild to moderate pain in adult and pediatric patients 2 years and older 2. Management of moderate to severe pain with adjunctive opioid analgesics in adult and pediatric patients 2 years and older 3. Reduction of fever in adult and pediatric patients.
  Company: B BRAUN MEDICAL

Drug Approvals: Europe

- RUKOBIA (FOSTEMSAVIR) was approved by the EMA to treat adults infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).
  Company: ViiV HEALTHCARE
- TUKYSA (TUCATINIB) was approved by the EMA to treat breast cancer that is locally advanced or metastatic (has spread to other parts of the body) and when it is HER2-positive.
  Company: SEAGEN
- LENALIDOMIDE KRKA (LENALIDOMIDE) was approved by the EMA for the treatment of certain cancers and serious conditions affecting blood cells and bone marrow, namely multiple myeloma, myelodysplastic syndromes and follicular lymphoma.
  Company: KRKA, D.D., NOVO MESTO
- LENALIDOMIDE KRKA D.D. (LENALIDOMIDE) was approved by the EMA for the treatment of certain cancers and serious conditions affecting blood cells and bone marrow, namely multiple myeloma, myelodysplastic syndromes and follicular lymphoma.
  Company: KRKA, D.D., NOVO MESTO
- LENALIDOMIDE KRKA D.D. NOVO MESTO (LENALIDOMIDE)
  was approved by the EMA for the treatment of certain cancers and serious conditions affecting blood cells and bone marrow, namely multiple myeloma, myelodysplastic syndromes, mantle cell lymphoma and follicular lymphoma.
  Company: KRKA, D.D., NOVO MESTO

Germany: Post-AMNOG Price Changes for Originator Drugs

Company	Product Group	Generic Name	Description	Start Date	MNF	OLD MNF	AMOUNT CHANGE
GSK	BENLYSTA	BELIMUMAB	BENLYSTA INFUSION 1 LYOPHILIZED POWDER VIAL 1.5 ML	02/15/21	130.05	130.19	-0.14
GSK	BENLYSTA	BELIMUMAB	BENLYSTA INFUSION 1 LYOPHILIZED POWDER VIAL 5 ML	02/15/21	433.50	434.00	-0.50
GSK	BENLYSTA	BELIMUMAB	BENLYSTA INJECTION 1 PREFILLED PEN 1 ML 200 MG	02/15/21	216.75	217.00	-0.25
GSK	BENLYSTA	BELIMUMAB	BENLYSTA INJECTION 12 PREFILLED PEN 1 ML 200 MG	02/15/21	2601.00	2604.00	-3.00
GSK	BENLYSTA	BELIMUMAB	BENLYSTA INJECTION 4 PREFILLED PEN 1 ML 200 MG	02/15/21	867.00	868.00	-1.00
AOP ORPHAN	BESREMI	ROPEGINTERFERON	BESREMI INJECTION 1 PREFILLED PEN 0.5 ML 250 MCG	02/01/21	1381.25	1382.25	-1.00
ASTELLAS	DIFICLIR	FIDAXOMICIN	DIFICLIR TABLETS 1 PACK 20 TABS 200 MG	02/15/21	1370.00	1455.63	-85.63
SANOFI	DUPIXENT	DUPILUMAB	DUPIXENT INJECTION 2 PREFILLED PEN 1.14 ML 200 MG	02/15/21	1163.86	1247.62	-83.76
SANOFI	DUPIXENT	DUPILUMAB	DUPIXENT INJECTION 2 PREFILLED PEN 2 ML 300 MG	02/15/21	1163.86	1247.62	-83.76
SANOFI	DUPIXENT	DUPILUMAB	DUPIXENT INJECTION 2 PREFILLED SYRINGE 1.14 ML 200 MG	02/15/21	1163.86	1247.62	-83.76
SANOFI	DUPIXENT	DUPILUMAB	DUPIXENT INJECTION 2 PREFILLED SYRINGE 2 ML 300 MG	02/15/21	1163.86	1247.62	-83.76
SANOFI	DUPIXENT	DUPILUMAB	DUPIXENT INJECTION 6 PREFILLED PEN 1.14 ML 200 MG	02/15/21	3491.59	3742.86	-251.27
SANOFI	DUPIXENT	DUPILUMAB	DUPIXENT INJECTION 6 PREFILLED PEN 2 ML 300 MG	02/15/21	3491.59	3742.86	-251.27
SANOFI	DUPIXENT	DUPILUMAB	DUPIXENT INJECTION 6 PREFILLED SYRINGE 1.14 ML 200 MG	02/15/21	3491.59	3742.86	-251.27
SANOFI	DUPIXENT	DUPILUMAB	DUPIXENT INJECTION 6 PREFILLED SYRINGE 2 ML 300 MG	02/15/21	3491.59	3742.86	-251.27
ROCHE	KADCYLA	TRASTUZUMAB	KADCYLA INFUSION 1 LYOPHILIZED POWDER VIAL 5 ML	02/01/21	1535.31	1615.99	-80.68
ROCHE	KADCYLA	TRASTUZUMAB	KADCYLA INFUSION 1 LYOPHILIZED POWDER VIAL 8 ML	02/01/21	2456.50	2585.58	-129.08
MERCK	PIFELTRO	DORAVIRINE	PIFELTRO TABLETS 1 PACK 90 TABS 100 MG	02/15/21	1388.53	1338.53	+50.00
ROCHE	TECENTRIQ	ATEZOLIZUMAB	TECENTRIQ INFUSION 1 VIAL 14 ML 840 MG	02/01/21	2329.07	2325.29	+3.78
ROCHE	TECENTRIQ	ATEZOLIZUMAB	TECENTRIQ INFUSION 1 VIAL 20 ML 1200 MG	02/01/21	3327.24	3321.84	+5.40

Drug Launches: Europe & U.S.

Country	Generic Name	Product Group	Company	Indication	Product Approval	Start Date (Launch)
FRANCE	SOLRIAMFETOL	SUNOSI	JAZZ	OBSTRUCTIVE SLEEP APNEA, NARCOLEPSY	16/01/2020	2/2/2021
SPAIN	APALUTAMIDE	ERLEADA	JANSSEN	NON-METASTATIC CASTRATION-RESISTANT PROSTATE	14/01/2019	1/2/2021
SPAIN	DAROLUTAMIDE	NUBEQA	BAYER	NON-METASTATIC CASTRATION-RESISTANT PROSTATE	27/03/2020	1/2/2021
UNITED KINGDOM	BREXUCABTAGENE	TECARTUS	GILEAD SCIENCES	MANTLE CELL LYMPHOMA (RELAPSED/REFRACTORY)	14/12/2020	1/2/2021
UNITED STATES	LISOCABTAGENE	BREYANZI	BRISTOL MYERS	LARGE B-CELL LYMPHOMA	N/A	5/2/2021
UNITED STATES	EVINACUMAB	EVKEEZA	REGENERON	HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA	11/2/2021	16/02/2021
UNITED STATES	TEPOTINIB	TEPMETKO	MERCK	NSCLC (MET EXON 14 SKIPPING)	3/2/2021	4/2/2021
UNITED STATES	UMBRALISIB	UKONIQ	TG THERAPEUTICS	MARGINAL ZONE LYMPHOMA, GIANT FOLLICULAR	5/2/2021	5/2/2021
UNITED STATES	VERICIGUAT	VERQUVO	MERCK	PREVENTION OF CARDIOVASCULAR COMPLICATIONS	19/01/2021	12/2/2021
GERMANY	FENFLURAMINE	FINTEPLA	ZOGENIX	DRAVET SYNDROME	18/12/2020	1/2/2021
GERMANY	INCLISIRAN	LEQVIO	NOVARTIS	HYPERCHOLESTEROLEMIA	9/12/2020	1/2/2021
GERMANY	PERTUZUMAB &	PHESGO	ROCHE	BREAST CANCER (HER2+)	21/12/2020	1/2/2021
GERMANY	ISATUXIMAB	SARCLISA	SANOFI	MULTIPLE MYELOMA (POMALIDOMIDE AND	30-05-200	1/2/2021
GERMANY	BALOXAVIR	XOFLUZA	ROCHE	INFLUENZA	7/1/2021	15/02/2021

Price Changes: Europe & U.S.

Country	Generic Name	Product Group	Company	Therapeutic Area	Avg. Price Change all SKU	First Pricing date
FRANCE	OLAPARIB	LYNPARZA	ASTRAZENECA	ONCOLOGY	-2.50%	24/01/2018
FRANCE	UPADACITINIB	RINVOQ	ABBVIE	IMMUNOSUPPRESSANTS	-6.25%	1/7/2020
FRANCE	BUPRENORPHINE & NALOXONE	SUBOXONE	INDIVIOR	NEUROLOGY	-19.89%	25/11/2009
GERMANY	PEGFILGRASTIM	CEGFILA	STADA	HEMATOLOGY	-24.41%	1/6/2020
GERMANY	TRASTUZUMAB EMTANSINE	KADCYLA	ROCHE	ONCOLOGY	-4.99%	1/1/2014
ITALY	DEXKETOPROFEN	ENANTYUM	FARMEDIA	RHEUMATOLOGY	3.98%	1/7/2018
ITALY	BROMAZEPAM	LEXOTAN	ROCHE	NEUROLOGY	4.86%	1/1/2017
ITALY	LORAZEPAM	TAVOR	GENERAL PHARMA	NEUROLOGY	5.74%	1/1/2017
UNITED STATES	CEMIPLIMAB	LIBTAYO	REGENERON PHARMACEUTICALS	ONCOLOGY	1.50%	28/09/2018
UNITED STATES	DOXEPIN	SILENOR	PERNIX THERAPEUTICS	NEUROLOGY	8.00%	1/2/2017

EVERSANA™ is the leading independent provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers.

The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science services for a healthier world. To learn more about EVERSANA, visit eversana.com.

Pricentric ONE by EVERSANA™ is a powerful intelligence tool that provides near real-time updates to drug price (list/net), reimbursement, and cost of treatment information at the indication level across 95+ markets and 250+ therapeutic areas. Visit us at pricentric.alscg.com.

UNITED STATES

Alan Crowther

General Manager, Global Pricing & Access

+1 (917) 749-4610

alan.crowther@eversana.com

Andrew Hanhauser

Vice President, Pricentric Leader

+1 (843) 801-4808

andrew.hanhauser@eversana.com

UNITED KINGDOM

Alan Stewart

Director, Account Services

+44 (0)7901 002066

alan.stewart@eversana.com

SPAIN

Miguel Espinosa

Director, Account Services

+34 673005073

miguel.espinosa@eversana.com