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Trump's MFN Rule Roll-Out Stalled by California, Maryland Courts

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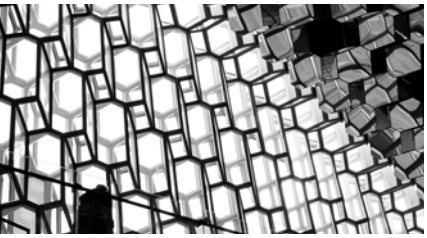
BMS, Roche, AZ Lose Out as China Favors Domestic Companies in NRDL PD-1 Battle

In the days before 2020 came to a close, China's National Healthcare Security Administration (NHSA) and Ministry of Human Resources and Social Security (MOHRSS) issued the 2020 Edition of the National Reimbursement Drug List (NRDL).



UK Makes Moves Toward Reforming Rare Disease Framework

At the beginning of January 2021, the UK's Department of Health and Social Care (DHSC) published a new 'UK Rare Disease Framework,' with hopes that the structure will help improve care for those who have rare diseases.

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Trump's MFN Rule Roll-Out Stalled by California, Maryland Courts

Date: January 5, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy | Keywords: #bio #executiveorder #hhs #lawsuit #medicare #mostfavorednations #phrma #referencepricing(irp)

PRICENTRIC BRIEF:

- District court judges in Maryland and Northern California have ruled to stall the implementation of President Donald Trump's "Most Favored Nations (MFN)" rule that was supposed to take effect on January 1, 2021
- MFN stipulates that the U.S. will pay the lowest price for certain Medicare-covered drugs among the following wealthy, developed nations that are part of the Organization for Economic Co-operation and Development (OECD): Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, and the United Kingdom
- Maryland District Court Judge Blake and Northern California District Judge Chhabria granted a nationwide temporary restraining order and a nationwide preliminary junction, respectively, halting the implementation of the MFN rule for 14 days on the grounds that the Department of Health and Human Services (HHS) bypassed the legal process by failing to give proper notice of MFN and allow for comments

THE DETAILS

WASHINGTON, D.C., The United States – This year seems off to a good start for pharmaceutical companies in the United States, as district court judges in Maryland and Northern California have ruled to stall the implementation of President Donald Trump's "Most Favored Nations (MFN)" rule that was supposed to take effect on January 1, 2021.

A radical policy change for the States, MFN stipulates that the U.S. will pay the lowest price for certain Medicare-covered drugs among the following wealthy, developed nations that are part of the Organization for Economic Co-operation and Development (OECD): Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, and the United Kingdom.

By paying the lowest price for prescription drugs among these countries, Trump expects Americans to save between 50% and 80% on their prescriptions.

The rule was supposed to take effect at the start of this year, although the Department of Health and Human Services (HHS) would continue to consider feedback from relevant stakeholders until January 26, 2021. However, the implementation of MFN will be stalled for 14-days.

Judge Catherine Blake of the District Court of Maryland granted a nationwide temporary restraining order against the MFN rule. According to the lawsuit, "The Centers for Medicare and Medicaid Services (CMS) did not provide the usual notice and comment period prior to promulgation of the rule. Instead, it found there was good cause to waive both the notice and comment period and the delay in effective date required under the Administrative Procedure Act (the "APA") and the Social Security Act because 'delaying implementation of this [rule] is contrary to the public interest[.]'"

CMS had argued that the need for affordable Medicare Part B drugs amidst the COVID-19 pandemic was reason enough to forgo notice and the comment period.

However, the plaintiffs – a bloc including community cancer centers and industry body PhRMA – contended that MFN will "cause immediate and irreparable harm to Medicare patients, healthcare providers, and pharmaceutical manufacturers," requested a temporary hold on implementing the rule to allow for more time to prepare for the new pricing model and attempt to negotiate new contracts—all amid a pandemic that has been stressing health care systems worldwide. District Judge Vince Chhabria of Northern California issued a similar ruling to Judge Blake, granting a nationwide preliminary junction.

The Biotechnology Innovation Organization (BIO), the California Life Sciences Association (CLSA), and BIOCOM California filed a challenge against the HHS targeting a lack of notice or opportunity for public comment prior to the attempted implementation of the policy, and an acknowledgment from the HSS, in its own rule, that it is unable to estimate the policy's potential impact on patients and providers.

The complaint also claimed that HHS lacks the authority to issue an administrative decree that makes broad changes to the statutory Medicare rules.

The agency never published a notice of proposed rulemaking, ruled Chhabria, the court unconvinced by the government's argument for bypassing necessary legal steps due to the pandemic.

A restraining order and preliminary injection were found to be in the best public interest, as opposed to fully implementing the MFN rule, which has been forecasted by EVERSANA data analysts to significantly impact the prices of drugs in the U.S.

During the two-week injunction, the Court will evaluate the legality of the MFN rule.

PCMA Sues Trump Administration Over Rebate Rule

Date: January 13, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy | Keywords: #executiveorder #hhs #medicare #negotiations #pbms #pcma #pharmacy #rebates #safeharborregulation

PRICENTRIC BRIEF:

- The Pharmaceutical Care Management Association (PCMA) has filed a lawsuit in the district court for the District of Columbia challenging the Trump Administration's Rebate Rule
- The lawsuit requests the court set aside the Rebate Rule introduced under the Administrative Procedure Act (APA) and declare that federal law protects the rebates that the Office of Inspector General, U.S. Department of Health and Human Services (HSS) are aiming to nix from the discount safe harbor regulation
- According to PCMA President and CEO JC Scott, "The Trump Administration's last-minute decision to finalize the rebate rule will drastically increase Medicare Part D premiums for seniors, while significantly increasing costs for taxpayers"

THE DETAILS

WASHINGTON, D.C., United States – The Pharmaceutical Care Management Association (PCMA) has filed a lawsuit in the district court for the District of Columbia challenging the Trump Administration's Rebate Rule.

The lawsuit requests the court set aside the Rebate Rule introduced under the Administrative Procedure Ac (APA) and declare that federal law protects the rebates that the Office of Inspector General, U.S. Department of Health and Human Services (HSS) are aiming to nix from the discount safe harbor regulation.

According to PCMA President and CEO JC Scott, "The Trump Administration's last-minute decision to finalize the Rebate Rule will drastically increase Medicare Part D premiums for seniors, while significantly increasing costs for taxpayers."

Scott continued, "The haphazard process to finalize a rule that had already been withdrawn circumvented the proper rulemaking process and imposes an effective date that utterly fails to take account of the CMS timeline for issuing implementing guidance, creating chaos for the upcoming plan year. In addition, the agency failed to consider the significant impacts on beneficiaries and government costs that were articulated in thousands of public comments opposing the rule when it was originally proposed. The rebate rule cannot be implemented and should be invalidated."

After the issuance of Trump's Executive Order on "Lowering Prices for Patients by Eliminating Kickbacks for Middlemen" from July 2020 that was seemingly disregarded, the Trump Administration managed to pass through the Rebate Rule in November, towards President Trump's incumbency.

The Rule allows for the exclusion of rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs) and Part D plans from safe harbor protection under the Anti-Kickback Statute (AKS), creating a new safe harbor protecting discounts reflected in the price of the drug at the pharmacy counter. Essentially, drugmakers and PBMs are prevented from negotiating rebates for prescription drugs, as the Rule creates new safe harbor protection for fixed-fee services arrangements between manufacturers and PBMs.

PCMA is arguing that Medicare Part D premiums will increase drastically, whereas they believe rebates actually lower medical costs. The Rebate Rule is one of the US's most expensive regulations ever, costing taxpayers $177 billion over ten years.

A poll conducted by PCMA found that Medicare Part D beneficiaries are concerned about the proposed changes to drug plans; specifically, senior registered voters enrolled in Part D said they'd be less likely to support reelection for their Congress members and other political candidates who support the rule.

UK Makes Moves Toward Reforming Rare Disease Framework

PRICENTRIC BRIEF:

- At the beginning of January 2021, the UK's Department of Health and Social Care (DHSC) published a new 'UK Rare Disease Framework,' with hopes that the structure will help improve care for those who have rare diseases
- A part of the reform, the DHSC plans to use the understanding gained from COVID-19 to ensure that the experiences of the rare disease community feed into the implementation of the priorities and wider framework
- The amendments hope to get patients a faster final diagnosis, increase awareness of rare diseases among healthcare professionals, improve coordination of care and improve access to specialist care

THE DETAILS

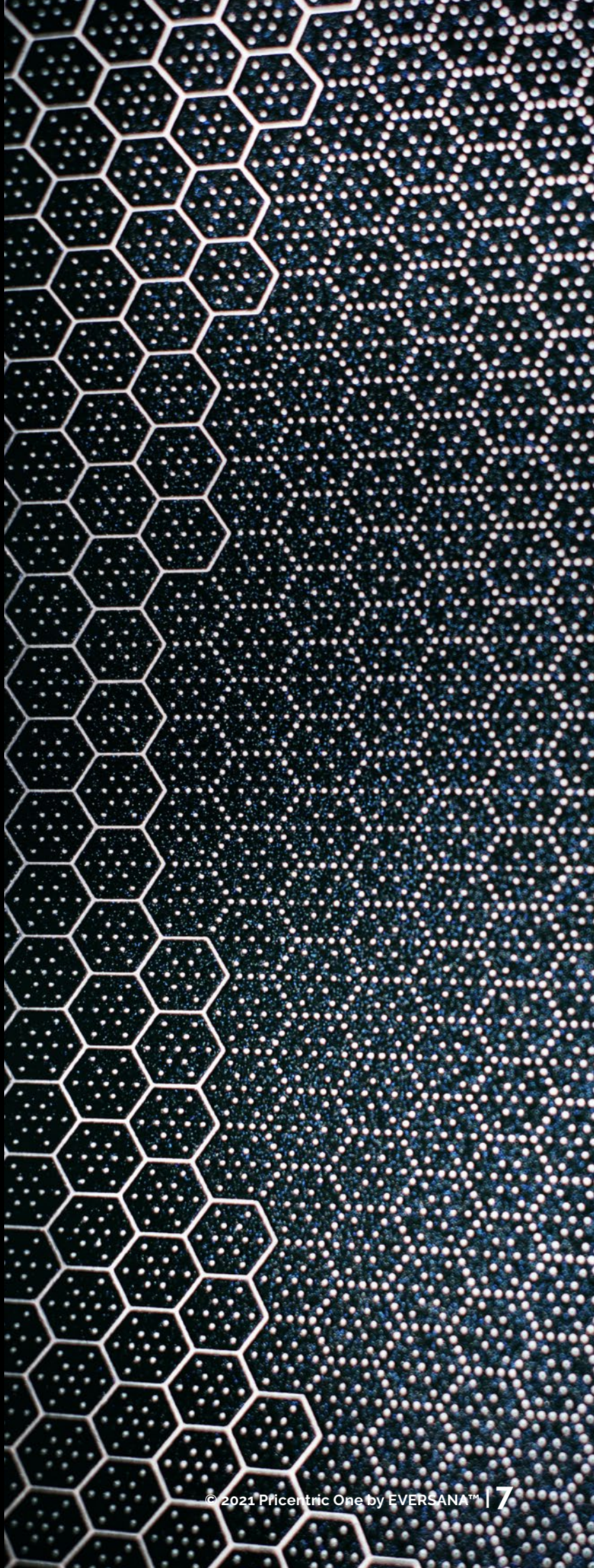
LONDON, United Kingdom – At the beginning of January 2021, the UK's Department of Health and Social Care (DHSC) published a new 'UK Rare Disease Framework,' with hopes that the structure will help improve care for those who have rare diseases.

Specifically, the guidance outlines four priorities for the UK over the coming five years:

- Helping patients get a final diagnosis faster
- Increasing awareness of rare diseases among healthcare professionals
- Better coordination of care
- Improving access to specialist care, treatments and drugs

The DHSC underlined that the framework is set to be implemented in two distinct phases. First, the document's release sets out a "high-level vision" for each of the above priority areas.

Following this, each nation will develop an action plan, highlighting steps they will take to meet the aims of the framework in accordance with their own arrangements.



COVID-19

The DHSC's plan also outlines how going forward, many of the UK's measures brought in due to COVID-19, such as the increased use of technology and virtual appointments, will be beneficial for the rare disease community in the long-term.

As such, the DHSC plans to use the experience gained from COVID-19 to ensure that the experiences of the rare disease community feed into the implementation of the priorities and wider framework.

Also, much like it did in its response to COVID-19, the Department highlighted how both national and international collaboration is essential to support research and patient care, especially for ultra-rare diseases.

Response & Support

Following recent survey findings that highlight remaining "major unmet needs" in the UK's rare disease landscape, Genetic Alliance UK and Alexion Pharma UK publicly supported the framework reform, calling on the Government and the NHS to take collaborative action to improve the quality of care for those living with a rare disease in the UK.

The survey, which was conducted by the All-Party Parliamentary Group (APPG), found that over one third (37%) would rate their overall experience of care as poor or very poor, and half (50%) of patients say that their care has not been effectively coordinated.

In addition to this, 52% of patients diagnosed in the last five years say they had to wait over two years for their diagnosis, with 41% waiting over five years, and almost half (49%) of patients having been misdiagnosed at least once, according to APPG.

Looking at the responses, the groups outlined five points of focus going forward:

As a first step, the Government and NHS should ensure that the implementation plans for the new Rare Disease Framework should be based on an evaluation as to why previous initiatives have failed to improve care in the last five years for all patients living with a rare disease.

The NHS must ensure it has the infrastructure in place to ensure that all patients suspected of having a rare disease are identified and able to access all the necessary diagnostic capabilities that the Genomic Medicine Service can offer.

The Government and the NHS should focus on improving whole-person care for patients with more complex conditions.

The NHS should provide every patient with a rare disease with (i) a dedicated care coordinator, (ii) access to a specialist center if available and (iii) a care plan if desired by the patient.

The NHS should put metrics and standards in place to ensure that decision making is shared with the patient, including improving access to relevant information about their condition.

Innovative Licensing and Access Pathway

The UK's Medicines and Healthcare products Regulatory Agency (MHRA), which is now the UK's standalone medicines and medical devices regulator as of 1 January 2021, also recently announced the implementation of its Innovative Licensing and Access Pathway (ILAP).

The new pathway has been created to help reduce the time it takes to get to market for innovative medicines, combining the MHRA's independence and high standards of quality, safety, and efficacy, with "improved efficiency and flexibility." The MHRA believes that the pathway will read the organization for a "new era in medicines approvals in the UK," according to a statement.

The project means that companies can now submit medicines from the 1st, following close collaboration between the NICE, drug regulators, the NHS, and equivalent organizations in Scotland.

BMS, Roche, AZ Lose Out as China Favors Domestic Companies in 2020 NRDL PD-1 Battle

PRICENTRIC BRIEF:

- In the days before 2020 came to a close, China's National Healthcare Security Administration (NHSA) and Ministry of Human Resources and Social Security (MOHRSS) issued the 2020 Edition of the National Reimbursement Drug List (NRDL)
- This year, PD-1 inhibitors - a category of drugs which are often costly yet highly effective - were the hot issue between multinational corporations (MNCs) and domestic businesses
- When the negotiations came to a close, home-grown PD-1 efforts from Shanghai Junshi Biosciences, Beigene Ltd and Jiangsu Hengrui Medicine took the coveted spots from household names like Roche, Bristol Myers Squibb, AstraZeneca and MSD

THE DETAILS

BEIJING, China – In the days before 2020 came to a close, China's National Healthcare Security Administration (NHSA) and Ministry of Human Resources and Social Security (MOHRSS) issued the 2020 Edition of the National Reimbursement Drug List (NRDL).

The scope of the 2020 NRDL considers what basic medical service (BMI) funds can afford considering clinical demands for drugs. Eligible drugs had to meet provisions outlined in Articles 7 and 8 of the Interim Measures for the Administration of BMI Medicines.

2020 NRDL Outcomes

The finalized 2020 NRDL, which comes into effect on March 1, 2021, contains 119 additional drugs across 31 therapeutic classes compared to the 2017 list - when the NHSA took hold of procurement - but has also removed 29. On average, pharma companies agreed to cut drug prices by 51%, on average, in order to gain access to the list. The Chinese market's promise of quantity is supposed to ultimately make up for the offset of the price cuts required to be on the NRDL

The 51% average cut is 10% lower than the 61% that was negotiated in in 2019, a welcome relief for both domestic and international companies that have consistently seen their prices lowered by the cut-throat bargaining of the Administration.

On the release of the list, the NHSA noted that a total of 704 non-2017 NRDL-listed drugs passed the initial application and review process for the 2020 list, among them 23 drugs (non-exclusive) were added to it directly and a further 138 exclusive drugs were eligible for negotiation towards addition.

The organization also confirmed that the 2020 list is ultimately made up of a total of 2,800 Western

medicines and proprietary Chinese medicines, including 1,264 Western medicines, 1,315 Chinese patent medicines, and 221 medicines negotiated during the agreement period.

Some key Western drugs that made the list include Novartis' Cosentyx (secukinumab), Teva Pharmaceutical's Austedo (deutetrabenazine) for Huntington's disease; AstraZeneca's oncology drug Zoladex (goserelin) and GlaxoSmithKline's Benlysta (belimumab) and Volibris (ambrisentan), for lupus and high blood pressure in the lungs, respectively.

This year a number of COVID-19 therapy recommendations are also now covered by the 2020 NRDL, including Arbidol and Ribavirin, which can be used to treat COVID-19 in China.

Instead, home-grown PD-1 efforts from Shanghai Junshi Biosciences, Beigene Ltd and Jiangsu Hengrui Medicine took the coveted spots. The three China-based companies offered up to a hefty 80% off the drugs' prices to win their places on the list, significantly more than the already staggering 64% that Eli Lilly offered to slash Tyvyt (sintilimab) by in the previous year's NRDL.

In 2019, Tyvyt – which is co-developed by Innovent and Lilly in China - was the only PD-1 to make the list, under the indication of relapsed/refractory classical Hodgkin's lymphoma after at least two lines of chemo.

After 2019 NRDL inclusion negotations wrapped, NHSA's Xiong Xianjun forecasted that price

Company	Drug Name	Drug Class	Dosage Form	Indication	Validity Period
BeiGene	**Baizean (tislelizumab)**	Monoclonal antibody	Injection	Classical Hodgkin's lymphoma treated with at least two prior therapies; Some locally advanced or metastatic urothelial carcinoma patients with PD-L1 high expression*	March 1, 2021 to December 31, 2022
Junshi Biosciences	**Tuoyi (teriprizumab)**	Monoclonal antibody	Injection	Unresectable or converted patients with previously failed systemic treatment of metastatic melanoma	March 1, 2021 to December 31, 2022
Hengrui Medicine	**camrelizuma**	Monoclonal antibody	Injection	Third-line treatment of recurr. or refract. classical Hodgkin's lymphoma; First-line treat. of non-squamous NSCLC; Hepatocellular carcinoma before Sorafenib treatment; Post-treat. progression in locally adv. or meta. esophageal squamous cell carc.	March 1, 2021 to December 31, 2022

* Whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

The Battle for PD-1 Placement

This year, PD-1 inhibitors - a category of drugs which are often costly yet highly effective - were the hot issue between multinational corporations (MNCs) and China. The group of checkpoint inhibitor anticancer drugs work by blocking the activity of PD-1 and PDL1 immune checkpoint proteins present on the surface of cells.

A spot on the NDRL is a sought-after prize for biopharma companies with innovative therapies like PD-1s trying to catch their break the Chinese market.

Following three-day negotiations that started on December 17, 2020 in Beijing, MSD's Keytruda (pembrolizumab), Bristol Myers Squibb's Opdivo (nivolumab), AstraZeneca's Imfinzi (durvalumab) and Roche's Tecentriq (atezolizumab) all failed to make their way into the finalized 2020 list.

negotiations for PD-1 cancer drugs would likely see intense competition next year (2020), given that medicines that find a place on the list are typically sold at the "lowest prices worldwide," said Xianjun.

The 2020 price reductions won Jiangsu's camrelizumab coverage for four indications, BeiGene's Baizean (tislelizumab) two indications and Junshi Biosciences' Tuoyi (teriprizumab) reimbursement in one indication.

At the time of the list's release, the prices were not officially disclosed, but Chinese media has since clarified them as the below:

- Hengrui Medicine's Camrelizumab (200 mg): CNY 3,000
- BeiGene's Tislelizumab (100 mg): CNY 1,500
- Junshi's Teriprizumab (80 mg): CNY 906

China has always been favorable of national drugmakers when choosing drugs for reimbursement. As such, it has an ongoing aim to ramp up production capabilities of domestic manufacturers, issuing guidance on which now off-patent medicines should be the focus of production and passing domestic manufacturers though generic quality and clinical equivalence evaluation (GQCE) to ensure their products are safe to market.

Looking to the future, the global market for PD-1/PD-L1 immunotherapy has been predicted to grow at a compound annual growth rate (CAGR) of 10.72% from 2020 to 2030, with a chance for the technology to become a prominent player in the cancer treatment landscape. However, as is the issue with many innovative drugs with a high price tag, PD-1s have various cost-related issues surrounding their market access pathways that need to be tackled.

NRDL Expansion

The NRDL has been updated annually since 2017 and has included some innovative therapies across various diseases to address clinical needs. In tandem, volume-based purchasing has been expanded nationwide, leading to a significant price reduction in the procurement.

Since then, the newly established NHSA Administration has greatly expanded access to medical care and drugs for the general population in China, with the NRDL being a key part of the success.

In November 2019, China made a key step in the direction of affordable, economical healthcare in the shape of expanding its NRDL, and the re-issued 2020 list is even wider-reaching.

Speaking at ISPOR Asia Pacific's virtual broadcast earlier this year, Gordon G Liu, PhD., National School of Development, Peking University, listed several other recent initiatives including Centralized Drug Negotiation, which consolidated drug price negotiation power at the national level, leveraging purchasing power and phased out PRDL.

He went on to highlight the now annual update of NRDL which expanded coverage for high cost and innovative drugs to alleviate the burden on patients due to previously high out of pocket costs, and Unified risk and funding pool which combined urban and rural residents' basic healthcare coverage and reduce coverage disparity.

With every NRDL update and increasing inclusion of drugs of a more innovative nature such as PD-1s, China cements itself further as an attractive drug launch destination for companies – a far cry from the 2017 edition of the NRDL which had not seen any development for the past eight years.

China and Its Innovative Future

China is making a number of other moves to boost its domestic generic drug manufacturing capabilities, mostly seen through its frequent issuance of guidelines calling for greater domestic production of much-needed and widely used off-patent medicines, and the same sentiment seems to be occurring with innovative medicines. This is particularly evident with the inclusion of the homegrown PD-L1s on the list; China opted to back locally manufactured immunotherapies as opposed to those produced by foreign drugmakers.

Overall, the 2020 NRDL criteria were more inclusive than 2019 set, meaning that the 2020 NRDL ultimately includes more innovative drugs. This is partly because of a revision made by the NHSA on August 17, 2020, which allowed drugs approved up to that date to submit NRDL applications, whereas the 2019 NRDL was only open to drugs that were launched in China before December 31, 2018.

The list is well on its way to becoming the most viable and exclusive pathway to get a product reimbursed on China's public health insurance.

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Canada Delays PMPRB Amendment Implementation to July 2021

Date: January 4, 2021 | Country: CANADA-ONTARIO | Region: NORTH AMERICA | Type: Policy | Keywords: #healthcanada #imc #pmprb #pricingandreimbursement #referencepricing(irp)

PRICENTRIC BRIEF:

- Initially having been set to take effect the first of this year, the implementation of the Patented Medicine Prices Review Board's amended regulations will be delayed once again to July 1, 2021, announced Health Canada
- PMPRB's elevated role and its strategy received backlash from industry and patient advocacy groups, all of whom fear the amendments will negatively impact the future of new drug launches and clinical trials due to PMPRB's more stringent pricing methodology
- Not only does the delay allow the industry and any relevant stakeholders to focus acutely on combatting the pandemic, it "provides the time and the opportunity for the government to work closely with industry, patients and other health system stakeholders on a better path forward," elaborated Innovative Medicines Canada (IMC)

THE DETAILS

OTTAWA, Canada – Health Canada announced that the implementation of the Patented Medicine Prices Review Board's amended regulations will be delayed once again to July 1, 2021.

The roll-out of the amendment has been delayed three times now; initially, it was supposed to take effect last year before being pushed back to July 2020, and then January 1, 2021, until, most recently, July of this year.

PMPRB's new role and its strategy received backlash from industry and patient advocacy groups, all of whom fear the amendments will negatively impact the future of new drug launches and clinical trials due to PMPRB's more stringent pricing methodology.

Innovative Medicines Canada (IMC) celebrated the delay, noting, "This is good news for Canadian patients concerned about the negative impact the regulations will have on their access to new medicines."

Additionally, not only does the delay allow the industry and any relevant stakeholders to focus acutely on combatting the pandemic, it "provides the time and the opportunity for government to work closely with industry, patients and other health system stakeholders on a better path forward," elaborated IMC.

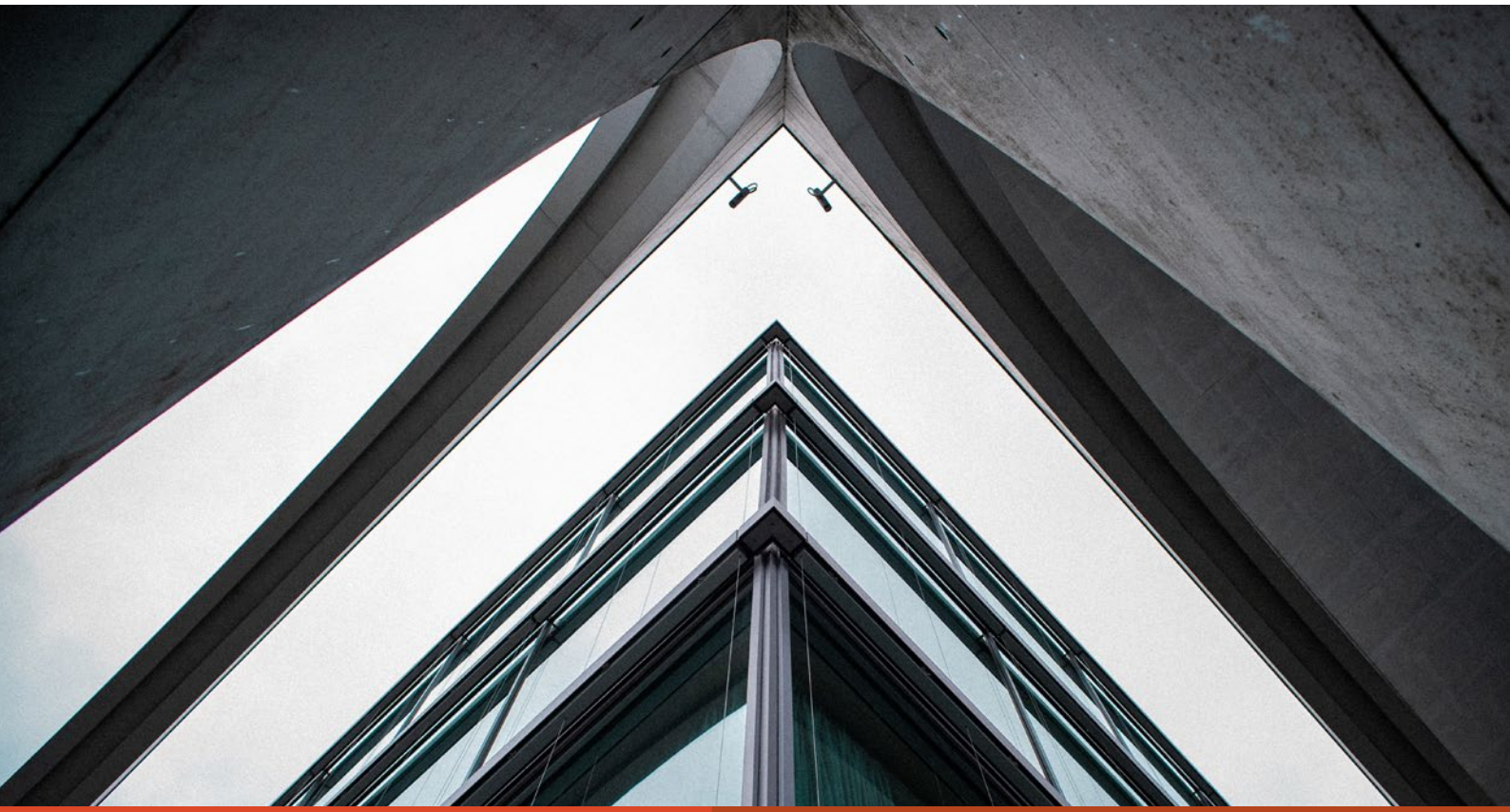
A Rundown of the PMPRB Amendment

The guidelines take aim at new, innovative medicines, whose projected treatment costs or sales surpass a certain threshold. The new guidelines propose a pharmo-economic value be applied to drugs to gauge how much improvement the drug offers over existing therapies.

Notably, drugs with a 12-month treatment cost surpassing 150% of GDP per capita and treatments with estimated or actual sales of more than CA$ 50 million per year will be required to undergo additional review, with the potential for price reductions of 20%-50% off list prices.

PMRPB specified that its new review would be applicable to a medicine depending on when it first received its eight-digit Drug Identification Number (DIN): Products that receive a DIN before January 1, 2021, will be grandfathered in, whereas those who obtain the DIN after this date will be subject to PMPRB review.

In addition, Canada's PMPRB will rely on an updated reference basket in which two countries where drug prices tend to often be higher – the United States and Switzerland – have been swapped out for markets where drug prices tend to be lower. Canada's basket will be composed of France, Germany, Italy, Sweden, and the UK, as well as newcomers Australia, Belgium, Japan, the Netherlands, Norway, and Spain.



FDA Approved 53 Novel Drugs in 2020

Date: January 7, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Drug Approval | Keywords: #biologics #cber #cderprojectorbis #fda #newmolecularentities #nme #oncology #rarediseases

PRICENTRIC BRIEF:

- Despite the pandemic ravaging the United States for most of 2020, the U.S. Food and Drug Administration managed to approve 53 novel drugs, according to the agency's yearly wrap-up
- The list includes new molecular entities (NMEs) and new therapeutic biologics approved by the FDA's Center for Drug Evaluation and Research (CDER), as well as innovative new products, some of which were never used before in clinical practice
- Most of the drugs intend to treat cancer or rare diseases, and some secured authorization from the FDA through Project Orbis, the FDA's collaborative initiative with regulatory agencies in Switzerland, Australia, Canada, and Singapore – and, most recently, Brazil and the United Kingdom

THE DETAILS

WASHINGTON, D.C., The United States – Despite the pandemic ravaging the United States for most of 2020, the U.S. Food and Drug Administration managed to approve 53 novel drugs, according to the agency's yearly wrap-up.

The list includes new molecular entities (NMEs) and new therapeutic biologics approved by the FDA's Center for Drug Evaluation and Research (CDER), as well as innovative new products, some of which were never used before in clinical practice.

Some drugs are classified as NMEs during FDA review as they contain active moieties previously not approved by the agency, either as a standalone drug or part of a combination.

However, as the FDA noted, the list excludes vaccines, allergenic products, blood and blood products, plasma derivatives, cell and gene therapy products, and products approved in 2020 by the

agency's Center for Biologics Evaluation and Research (CBER).

Most of the drugs intend to treat cancer – for example, Roche's Gavreto (pralsetinib) for non-small cell lung cancer (NSCLC) and Deciphera's Qinlock (ripretinib) for advanced gastrointestinal-stromal tumors (GIST) – or rare diseases, including Roche's Evrysdi (risdiplam) for spinal muscular atrophy (SMA) and Alnylam's Oxlumo (lumasiran). Gilead's COVID-19 antiviral Veklury (remdesivir) also found a place on the FDA's list, a nod to the success of pharmaceutical companies in producing treatments amidst the pandemic.

But overall, the majority of these approved innovative medicines target cancer. Medicines such as Sanofi's Sarclisa (isatuximab) and Seagen's Tukysa (tucatinib) were greenlighted through Project Orbis, a collaborative initiative of the FDA's Oncology Center of Excellence that allows for concurrent submission and review of oncology drugs among the regulatory agencies of the U.S., Switzerland, Australia, Canada, and Singapore – and Brazil in 2020 and the United Kingdom at the start of this year.

All in all, the FDA's recap of its new drug approvals for 2020 speaks to the evolution of medicine in combatting tough-to-beat, life-threatening diseases and conditions, and the FDA's willingness to greenlight innovative medicines. It will be interesting to see how Trump's "Most-Favored Nations (MFN)" rule, if kept, impacts future drug approvals in the U.S., as it augments how drugs will be priced in the U.S. by utilizing a reference pricing system, a radical change for the States.

For the FDA's full list of 2020 innovative drug approvals, click here.

Tennessee Approved for Medicaid Block Grant in Move Not Aligned with Biden's Healthcare Proposals

Date: January 11, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy | Keywords: #administration #biden #block #democrat #elect #grant #medicaid #medicare #obamacare #president #repeal #republican #states #tennessee #trump

PRICENTRIC BRIEF:

- Tennessee has become the first state in the United States (U.S.) to be approved to receive a lump sum of funding for its Medicaid program, through a "Block Grant" waiver amendment
- As of the decision, Tennessee has additional freedom over the use of its federal Medicare funding, but the block grant also caps the funding that the state is allowed
- The change comes at an interesting juncture, just ahead of Biden – who fundamentally opposes the plan due to his planned expansion of Obamacare - officially being sworn in as U.S. President a couple of weeks from now

THE DETAILS

TENNESSEE, United States - Tennessee has become the first state in the United States (U.S.) to be approved to receive a lump sum of funding for its Medicaid program, through a "Block Grant" waiver amendment.

The authorization follows over a year of negotiation between the Centers for Medicare and Medicaid Services (CMS) and the federal government, during which TennCare submitted Amendment 42 to CMS in November 2019.

As of the decision, Tennessee has additional freedom over the use of its federal Medicaid funding, but the Block Grant also caps the funding that the state is allowed.

As it stands in Tennessee's system, the federal government covers Tennessee for approximately two-thirds of the cost of TennCare - uncapped, meaning that the federal funding adjusts upwards or downwards, dependent on rising or falling TennCare costs.

If the amendment is officially signed off by Tennessee's state legislature, the approval could last 10 years.
Trump Administration Vs. Biden Presidency

The change comes at an interesting juncture, just ahead of Biden – who fundamentally opposes the plan due to his planned expansion of Obamacare - officially being sworn in as U.S. President a couple of weeks from now.

Governor Bill Lee said that the agreement represents a "continuation of Tennessee's commitment to innovate, lead and improve. We have sought to fundamentally change an outdated and ineffective Medicaid financing system that incentivizes states to spend more taxpayer dollars rather than rewarding states for value, quality and efficiency."

He continued, "Our approved plan will create an unprecedented opportunity for Tennessee to be rewarded for its successful administration of TennCare and further improve the health of TennCare members and Tennessee communities with that reward."

However, the proposal still needs final approval from state lawmakers before it can be officially implemented. Not only does it need the green light from lawmakers, but President-elect Joe Biden also has the opportunity to repeal the decision if he determines that it does not align with his healthcare vision.

The Texan Governor's office has disclosed that the Block Grant's priorities include mental health services, as well as those with disabilities who are still waiting on treatment and services.

Controversial Changes Met with Scepticism

The Trump administration-approved policy change has been met with varying degrees of support, with Stephen Smith, director of Tennessee's Medicaid program reassuring that there will not be a reduction in services available due to the change.

Michele Johnson, executive director of the Tennessee Justice Center, raised another point when she noted in an interview: "As far as I can see, the agreement gives Tennessee a lot of flexibility to do things that would result in less people covered and less protection for those people who are covered. If they don't intend to do that, why seek the flexibility to do it?"

She went on to denounce the proposal, suggesting the Block Grant is "just another example of putting politics ahead of health care during this pandemic," exclaiming, "Now is absolutely not the time to waste our energy and resources limiting who can access health care."

When the governor initially proposed the changes last year, Texas collected approximately 1,800 written comments on the Block Grant, of which only 11 expressed support for the plans.

CMS Final Rule Provides Breakthrough Medical Devices Medicare Coverage Upon Receiving FDA Approval

Date: January 14, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy | Keywords: #breakthroughstatus #cms #coverage #drugapproval #fda #innovation #mcit #medicaldevices #medicare #medicarecoverageofinnovativetechnology #pricingandreimbursement #realworldevidence #regulation

PRICENTRIC BRIEF:

- The Centers for Medicare & Medicaid Services (CMS) has announced "The Medicare Coverage of Innovative Technology (MCIT)" final rule establishing a new, accelerated Medicare pathway for innovative medical devices and products designated "Breakthrough" status by the U.S. Food and Drug Administration (FDA) that allows for simultaneous coverage of these products upon receiving FDA approval for four years
- The rule – which took effect January 12, 2020 – applies to all FDA decisions from the date of effectivity, as well as devices granted breakthrough designation from two years prior to the date
- Once the four-year period wraps, CMS will assess the product in questions based on clinical and real-world evidence (RWE) to determine if the coverage should be permanent

THE DETAILS

WASHINGTON, D.C., The United States – The Centers for Medicare & Medicaid Services (CMS) has announced "The Medicare Coverage of Innovative Technology (MCIT)" final rule establishing a new, accelerated Medicare pathway for innovative medical devices and products designated "Breakthrough" status by the U.S. Food and Drug Administration (FDA) that allows for simultaneous coverage of these products upon receiving FDA approval for four years.

The rule – which took effect January 12, 2020 – applies to all FDA decisions from the date of effectivity, as well as devices granted breakthrough designation from two years prior to the date.

Once the four-year period wraps, CMS will assess the product in questions based on clinical and real-world evidence (RWE) to determine if the coverage should be permanent. CMS believes this rule will incentivize manufacturers of breakthrough devices to develop additional evidence supporting continued coverage, beyond the four-year timeline.

The rule also harmonizes the local coverage determination (LCD) which, until recently, led to unequal coverage and access for seniors based on residency. MCIT cuts the requirement for manufacturers to seek decisions from Medicare's 16 administrative contractors (MACs), ending previous practices in which devices could be covered in one area of the country but not another, in the absence of national Medicare coverage decisions.

Going forward, innovators will no longer need to seek LCDs from each MAC; instead, they have the option to select when they would like coverage to begin, this flexibility offering them to align the coverage process with their own manufacturing and distribution cycles.

CMS Administrator Seema Verma commented, "Government processes have slowed beneficiaries' access to innovative treatments. Despite being deemed safe and effective by the FDA, Medicare beneficiaries have not had predictable, immediate access to innovative breakthrough devices.

"In an ever-evolving health care marketplace, CMS remains committed to transforming the health care delivery system through initiatives like MCIT that focus on results, removing government barriers to advancing innovations, fostering competition, and ensuring quicker access to the most advanced therapies for Medicare beneficiaries while providing them with better value and outcomes," concluded Verma.

CMS Aims to Combat Health Disparities, Improve Home Health Care, Lower Drug Prices, & Ease Into VBP Contracts

Date: January 20, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy | Keywords: #based #chip #cms #homehealthcare #medicaid #medicare #negotiation #payment #pbm #rebate #sdoh #value #vbp

PRICENTRIC BRIEF:

This month, the U.S. Centers for Medicare & Medicaid Services (CMS) unveiled a slew of regulatory changes including the integration of social, environmental, and economic factors in health care and the expansion of value assessments for health care based at home

Another rule enables Medicare enrollees to compare out-of-pocket costs for various prescription drugs in order to score a better deal

In late December 2020, CMS also finalized regulatory revisions that will empower states, private payers, and drugmakers with new methods of entering value-based purchasing arrangements (VBPs)

THE DETAILS

WASHINGTON D.C., The United States – This month, the Centers for Medicare & Medicaid Services (CMS) unveiled a slew of regulatory changes including the integration of social, environmental, and economic factors in health care, the expansion of value assessments for home health care, and the introduction of a digital tool for Medicare enrollees to compare out-of-pocket costs for various prescription drugs.

In late December 2020, CMS also finalized regulatory revisions that will empower states, private payers, and drugmakers with new methods of entering value-based purchasing arrangements (VBPs). Below these regulations are explained.

Considering Social Determinants of Health (SDOH)

CMS on January 7, 2021 published guidance for state health officials on the importance of enacting strategies that improve beneficiary health outcomes, minimize health disparities and reduce the costs of Medicaid and the Children's Health Insurance Program (CHIP).

Specifically, the strategies for Medicaid tackle social determinants of health (SDOH), which encompass social, environmental, and economic factors that can strongly impact an individual's health.

"The evidence is clear: social determinants of health, such as access to stable housing or gainful employment, may not be strictly medical, but they nevertheless have a profound impact on people's wellbeing," said CMS Administrator Seema Verma.

Studies have shown that these factors can worsen an individual's health, leading to more expensive health care, thus reinforcing disparities in health across the disabled, the elderly, pregnant women, young people, those with mental health disorders or substance abuse disorders, and residents of rural areas. The COVID-19 pandemic is causing an additional disproportionate impact on these groups.

The SDOH guidance explores how state Medicaid and CHIP programs can boost beneficiary outcomes through various approaches to delivery, benefits, and methods of reimbursement. Certain services can be designed to fit the specific priorities of a state. Additionally, the guidance covers housing-related and educational services, non-medical transportation, home-delivered meals, and employment assistance.

Home Health Value-Based Purchasing (HHVBP) Model Expansion

The following day, CMS announced that it certified expansion of the Home Health Value-Based Purchasing (HHVBP) Model starting in 2022. Already enacted in nine states, the model has boosted the quality scores of home health agencies by 4.6% and saved Medicare an average of $141 million annually.

"The Coronavirus pandemic has tragically illustrated how important it is for elderly Americans to have a robust set of options outside of nursing homes," commented Verma.

Originally introduced in 2016, the gist of the HHVBP Model is to improve the quality of home health

services through payment incentives. Quality performance measures of an agency are compared to those of other home health services in the same state.

States in which all Medicare-certified HHAs participate in the model include Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington.

A report evaluating the model's performance from 2016 through 2018 demonstrated that it did in fact improve quality of care without introducing significant provider burden or adverse effects on patient access, paving the way for its future expansion.

Further, the report demonstrated improvement in functional status for home health patients, and observed reductions in unplanned acute care hospitalizations and skilled nursing facility (SNF) visits, resulting in reductions in inpatient and SNF spending, partially offset by an increase in annual emergency department (ED) spending.

Medicare Advantage and Part D Prescription Drug Program Modernization

CMS finalized, this month, changes to Medicare Advantage and Part D prescription drug programs starting in 2022. Cost-sharing for enrollees is expected to fall for certain expensive drugs. The rule will allow individuals who are enrolled to compare out-of-pocket costs for various prescription drugs through a digital tool.

The federal government hopes to save over $75 million over the next decade, as a result of these revisions.

The rules follow a CMS requirement that went into effect January 1, 2021, launching employment of a prescriber real-time drug benefit tool for Part D plans. Congress also recently mandated prescriber real-time benefit tools in the Consolidated Appropriations Act, 2021 (Public Law No. 116-260).

The new rule will introduce on formularies a second, "preferred" specialty tier with a lower cost-sharing level than a standard specialty tier, enabling Part D plans to negotiate better drug prices with manufacturers.

Moreover, Part D plans must now disclose pharmacy performance measures to CMS, and CMS will be able to publicly release this information to foster transparency and facilitate a better understanding of the impact of its measures, particularly on pharmacy reimbursements.

Medicaid Prescription Drug Purchasing & Payment Models

In late December 2020, CMS finalized regulatory revisions that will empower states, private payers, and drugmakers through new avenues to entering value-based purchasing arrangements (VBPs).

"Rules on prescription drug rebates and related reporting requirements have not been updated in thirty years, and are thwarting innovative payment models in the private sector," explained Verma.

Specifically, the new regulations allow payers to negotiate prices with drugmakers for gene-therapies based upon outcomes and evidence-based measures like reduced hospitalizations, lab visits, and physician office visits.

Manufacturers can also report a handful of best prices instead of a single best price when presenting VBP arrangements to states, allowing for more effective experimentation with value-based arrangements. This rule may come to fruition as soon as March 2021.

It is expected that federal and state governments will save $228 million through the year 2025, as a result of these new regulations.

Some critics, however, worry that the best price regulation will remove guaranteed best price discounts which make prescription drugs affordable to Medicaid beneficiaries. Forbes also warned that value-based contracts don't guarantee a decline in drug prices because they simply aim to align price and value.

Additionally, new programs have been introduced to assist in opioid utilization and addiction recovery and help states identify the inappropriate prescribing of opioids to at-risk patients.

Further new policies clarify the definition of line extension drugs may result in savings of $2.3 billion in the form of additional manufacturer rebates to states, through the year 2025.

The new rules also crack down on instances where prescription drug discounts do not benefit the patient and instead cut costs for health insurance companies and their pharmacy benefit managers (PBMs).

Such instances must be recorded in the drugmaker's reporting to CMS for Medicaid rebate purposes. This particular rule, however, will not go into effect until January 1, 2023, in order to give manufacturers and payers time to prepare.

Saudi Arabia Rolls Out New Pricing Guidelines

Date: January 19, 2021 | Country: SAUDI ARABIA | Region: MIDDLE EAST | Type: Policy | Keywords: #biosimilars #budgetimpact #costeffectiveness #drugcombination # generics #hta #innovativedrugs #negotiations #orphandrugs #pricereductions #pricingandreimbursement #referencepricing(irp) #repricing #risksharingagreements #sfda

PRICENTRIC BRIEF:

- On January 14, 2021, the Kingdom of Saudi Arabia introduced new pricing policy, updating guidelines for determining the prices of medicines and reorganizing the Kingdom's reference basket
- The Kingdom's updated reference basket now includes Australia, Austria, Belgium, Brazil, Canada, France, Hungary, Ireland, Italy, Japan, Jordan, Lebanon, Netherlands, Portugal, South Africa, South Korea, Sweden, Switzerland, the United Arab Emirates (UAE), and the United Kingdom
- According to EVERSANA Data Analyst Aatiqah Thanvi, "As part of their 2030 reforms, [Saudi Arabia] has introduced flexible pricing measures which make the market more appealing for companies to launch in Saudi Arabia first. They are allowing companies more flexibility in terms of price, which was never the case. Pricing mechanisms such as risk-sharing agreements are now being widely used, advantaging orphan drugs (e.g. fast-track process but also price premiums). More importantly, they are becoming the literal king in the region, as

THE DETAILS

RIYADH, Saudi Arabia – The Kingdom of Saudi Arabia (KSA) has introduced new pricing policy, updating guidelines for determining the prices of medicines and reorganizing the Kingdom's reference basket.

These changes took effect on January 14, 2021.

In regard to reference pricing (IRP), Saudi Arabia has shrunk its basket from 30 countries to 20, removing Algeria, Argentina, Bahrain, Cyprus, Denmark, Egypt, Germany, Greece, Kuwait, New Zealand, Oman, Spain and Turkey, and adding Brazil, Austria, South Africa. The Kingdom's updated reference basket now includes Australia, Austria, Belgium, Brazil, Canada, France, Hungary, Ireland, Italy, Japan, Jordan, Lebanon, Netherlands, Portugal, South Africa, South Korea, Sweden, Switzerland, the United Arab Emirates (UAE), and the United Kingdom.

Of note, Saudi Arabia may review its reference basket on a case-by-case or per-product basis and could pick a country where the product has been launched that is not included in the basket.

When it comes to pricing innovative drugs, the Saudi Food and Drug Administration (SFDA) can pursue either following the company's proposed export price, which will most certainly lead to negotiations and could result in a reduced price, or clinical comparison studies and pharmacological economics with registered therapeutic alternatives, as long as the price of the therapeutic alternative does not exceed the equivalent, neither in Saudi Arabia or its reference countries.

For the latter option the pricing committee can pursue, budget impact models are crucial for achieving a higher price against therapeutic alternatives.

If a therapeutic alternative is not available or registered in Saudi Arabia, the Kingdom will look at the product price based on weight in countries where it is marketed, and the committee will consider the use of economic models (health technology assessment; HTA) to support a high price.

These pricing rule changes extend to combination preparations, as well as generics and biosimilars. For combinations, the price should not exceed that of the price of the first preparation including add-ons.

The prices of first generics and biosimilars have been set with a mandated discount that applies for subsequent products as well.

For generics, the price of the innovator and all concentrations and packages will be reduced by 25% upon the advent of the first generic product. The first generic cannot exceed 70% of the price of the innovator, whereas the second will be priced at 65% and the third 60% of that price.

For biosimilars, the innovator – again, all concentrations and packages – will be reduced by 20% upon the advent of biosimilar competition. Similarly to generics, the first biosimilar's price cannot exceed 75% of the registered price of the reference product before the mandated reduction, and the prices of the second and third biosimilars, should be 65% and 55% of that price, respectively.

Price reviews can occur every two years if the medicine is "expensive," and companies can request a new price if their drug is registered if prices change elsewhere, in the country of origin or where it's marketed, or the company can justify a price change.

According to an experienced local Saudi healthcare access and pricing expert interviewed by EVERSANA, "With the present guidelines, SFDA has oriented its decision making towards more value-based assessment, without unlocking fully from the IRP system. Main changes include the engagement of health economic studies and anchoring to local comparators, whereas the reference list was reduced to 20 countries.

"Other innovative clauses favor early registrations in Saudi Arabia within the global submission plans of the industry, and also favor orphan and innovative medicines through a fairer pricing mechanism. SFDA certainly did not neglect increasing budget savings by presenting clauses that (1) endorse local manufacturing, (2) augment the brand price decrease after first generic entry, and (3) include new repricing mechanisms.

"With the present guidelines, and understanding the impact of the Saudi pricing on MENA and beyond, SFDA is sending a message that KSA is holding a strong position as an influential global player in the healthcare and pharma industry; better said, as 'Price Makers instead of Price Takers,'" concluded the expert.

EVERSANA Data Analyst Aatiqah Thanvi added, "Saudi has finally excluded countries such as Egypt, Turkey, and Argentina in their reference basket, which have caused extreme downward price impact. But one should not forget: Saudi, as a country, is very informal and, therefore, upon establishing the list price, they may look outside the reference basket on a case-by-case basis."

Thanvi further stated, "As part of their 2030 reforms, they have introduced flexible pricing measures which make the market more appealing for companies to launch in Saudi Arabia first. They are allowing companies more flexibility in terms of price, which was never the case. Pricing mechanisms such as risk-sharing agreements are now being widely used, advantaging orphan drugs (e.g. fast-track process but also price premiums). More importantly, they are becoming the literal king in the region, as they are becoming more HTA-focused (budget-impact, cost-effectiveness models used to establish price). Saudi even has an informal cost-effectiveness threshold."

AIFA Approves New Pricing, Reimbursement Negotiation Guidelines for Italy Following Years of Discussion

Date: January 5, 2021 | Country: ITALY | Region: NORTH AMERICA | Type: Pricing & Reimbursement | Keywords: #aifa #decree #implementation #legislation #negotiation #pricing #reimbursement

PRICENTRIC BRIEF:

- The Italian Medicines Agency (AIFA) has officially approved new legislation set to overhaul the way pharmaceuticals are priced in Italy, following an announcement that dates back to July 2020
- The criteria and procedures are set to begin from March 21, 2021, in order to give stakeholders a suitable transition period for the compilation of the new dossier
- The provision, which was signed by then ministers Giulia Grillo (Health) and Giovanni Tria (Economy) in August 2019, will introduce new "Criteria and methods by which the Italian Medicines Agency determines, by negotiation, the prices of drugs reimbursed by the Service national health"

THE DETAILS

ROME, Italy – The Italian Medicines Agency (AIFA) has officially approved new legislation set to overhaul the way pharmaceuticals are priced in Italy, following an announcement that dates back to July 2020.

The criteria and procedures are set to begin from March 21, 2021, in order to give stakeholders a suitable transition period for the compilation of the new dossier.

In September 2020, AIFA published draft guidelines and launched a two-week consultation where interested parties had the opportunity to comment on new "guidelines for the compilation of the dossier supporting the application for price and reimbursement." The deadline for the consultation was September 30, and AIFA then released the final document.

The objective of the reform is to lower costs of innovative medicines to the Italian NHS by tweaking the criteria and procedures used in pricing and reimbursement. With the reform, the price will no longer be based on a favorable cost-effectiveness ratio, thus shifting to added therapeutic value compared to treatments already available on the market.

The AIFA evaluation would take 180 days, rather than 90 days, and a "stop clock" has been introduced.

Details of the Decree

The provision, which was signed by then ministers Giulia Grillo (Health) and Giovanni Tria (Economy) in August 2019, will introduce new "Criteria and methods by which the Italian Medicines Agency determines, by negotiation, the prices of drugs reimbursed by the Service national health."

The new decree officially repeals a resolution that was implemented in February 2001, which established the initial criteria and methods for negotiating the prices of medicines.

The adoption of new policies responds to the need to introduce updated and adequate criteria for the evolution of drug policy and in compliance with the necessary transparency, according to the country's Ministry of Health, which also stressed that "among the novelties, there is the emphasis placed on the added therapeutic value that the medicine must ensure in relation to the main treatments with which it is compared."

Further changes mean that companies will be asked to prove their production capacity and management of possible unexpected events, as well as to anticipate the activities it intends to implement to ensure the adequate supply of the drug.

Following the new policy, to negotiate a drug's price, a drugmaker must provide the Italian Medicines Agency (AIFA) with a series of documents:

- Scientific documentation from which emerges the possible added therapeutic value of the medicine, in relation to therapeutic alternatives used in national clinical practice, including an evaluation of the costs of alternative treatments, the dosage schedules and the duration of the treatments must be clarified;
- The documentation providing economic evaluation, according to the previous indications;
- Self-certified information elements on the medicine about marketing, consumption and reimbursement in other countries, and in this case at what price and reimbursement conditions, including any further negotiation agreement;
- The annual market shares expected to be acquired in the subsequent thirty-six months in the specific market segment;
- Self-certification of the company on its production capacity and management of possible unforeseen events that could jeopardize production standards and activities to guarantee the adequate supply of the drug to the National Health Service (SNS) according to the needs of the population;
- The forecast and the changes in expenditure for the National Health Service deriving from the proposed prices, in the components list;
- Self-certified quantification of any public contributions and incentives aimed at drug research and development programs;
- Quantification of the economic-financial impact on the National Health Service and related consumption resulting from the inclusion in early access programs;
- Quantification of the economic-financial impact and related consumption resulting from marketing;
- Any other information useful for negotiation, including the patent status of the medicinal product.

The negotiation procedure is concluded by an agreement between AIFA and the drugmaker, with the fixing of the conditions of reimbursement and price, in accordance with the provisions established by the decree and taking into account certain conditions such as sales volumes, the availability of the product on the SSN, discounts for supplies to the institutions of the SSN, and any public contributions to drug development and research programs.

Under the newer rules, scoring reimbursement in Italy will be contingent upon demonstration of a drug's added value in light of therapeutically comparable drugs.

Going forward, Italy's Scientific Technical Committee (CTS) may also introduce limitations on reimbursement to ensure greater appropriateness of use or to identify specific areas of use.

During the price negotiation phase, AIFA is now required to consider, based on the presumable consumption data, also the financial constraints envisaged by the current legislation on pharmaceutical expenditure.

The new pricing procedure will affect medicines authorized using the centralized, mutual recognition, decentralized and national procedures.

Italy Reimburses Novartis' Luxturna for Hereditary Retinal Disease

Date: January 22, 2021 | Country: ITALY | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #aifa #cellandgenetherapy #earlyaccess #innovativedrug #novartis #payback #pediatrics #specialfund #spendingceiling #ssn

PRICENTRIC BRIEF:

- The Italian Medicines Agency (AIFA) has given the go-ahead to reimburse Novartis' ophthalmic gene therapy Luxturna (voretigene abeparvovec) for treating hereditary dystrophy in pediatric and adult patients with vision loss due to confirmed biallelic mutation of the RPE56 gene who have sufficient, viable retinal cells
- As an innovative medicine, Luxturna will be paid for through Italy's special fund for non-oncology medicines whose reserve consists of €500 million
- A spending cap of €21.6 million over 24 months has been put in place, which includes any previous spending on the gene therapy, even costs incurred via early access schemes, and if this threshold is crossed within this timeframe, net of any discounts achieved through negotiation, the excess will be refunded through payback

THE DETAILS

ROME, Italy – The Italian Medicines Agency (AIFA) has given the go-ahead to reimburse Novartis' ophthalmic gene therapy Luxturna (voretigene abeparvovec) for treating hereditary dystrophy in pediatric and adult patients with vision loss due to confirmed biallelic mutation of the RPE56 gene who have sufficient, viable retinal cells.

The decision to reimburse Luxturna under the national health service (SSN) took effect January 10, 2021.

The ex-factory price (excluding VAT) of Luxturna is €360,000. A spending cap of €21.6 million over 24 months has been put in place, which includes any previous spending on the gene therapy, even costs incurred via early access schemes. If this threshold is crossed within this timeframe, net of any discounts achieved through negotiation, the excess will be refunded through payback.

Novartis was the recipient of the Prix Galien Italia 2019 prize for "Medicines for Advanced Therapy" for Luxturna due to its innovativeness. As an innovative medicine, it will be paid for through Italy's special fund for non-oncology medicines whose reserve consists of €500 million.

As reported by About Pharma, two children have so far been treated with Luxturna at the Ophthalmology Clinic of the University of Campania Luigi Vanvitelli. Now that the treatment is being reimbursed, ophthalmologists are eager to administer it to more patients.

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Moreno Announces End to Andalusia Drug Auction

Date: January 5, 2021 | Country: SPAIN | Region: EUROPE | Type: Tender | Keywords: #drugauction #farmaindustria #policy #pricingandreimbursement

PRICENTRIC BRIEF:

- President of Andalusia, Juan Manuel Morena has declared an end to drug auctions in Andalusia
- Moreno's announcement puts an end to planned amendments to the drug auction, which has been criticized for limiting access to medicines and causing drug shortages
- Humberto Arnes, CEO of Farmaindustria, said, "We interpret that access in Andalusia will be the same as in the rest of Spain and we interpret that the recent modification of the Andalusian Pharmacy Law remains a dead letter"

THE DETAILS

SEVILLE, Andalusia, Spain – President of Andalusia, Juan Manuel Morena has declared an end to drug auctions in Andalusia.

Morena stated that Andalusia will no longer continue this practice, "a system that we promised to change because it supposed a disguised cut in the rights of Andalusians to access to medicines and a clear interference with the freedom of prescription and placed Andalusians in a situation of inequality compared to other Spaniards."

The Andalusian Ministry of Health previously expressed its intent to augment the auction system and talks were held in the beginning of 2020 to decide on a new path for the system. In the past Andalusia's drug auction has been controversial because it has caused shortages and a lack of adherence in patients to their medicines.

Andalusia Parliament's Finance Commission even went as far as approving an amendment to the community's tendering procedure, securing votes from various political parties. The decision was not final, though, as it needed to be approved in the Budget Report and debated by the Finance Commission.

Under the proposal, exclusive awards would be avoided, a minimum improvement percentage would be established, pharmacies would be able to choose the medicine to be dispensed from among all those selected, and the holding of calls would not be mandatory.

The Andalusian Business Confederation of Pharmacy Offices (Ceofa) also issued a statement in response to the new auction of medicines in Andalusia proposal, in which it expressed its "resounding rejection" of the implementation of the plan.

Elated by the announcement to scrap Andalusia's auction, Humberto Arnes, CEO of Farmaindustria, said, "From now on there will be no difference in access to medicines by any Andalusian." Arnes added, "We interpret that access in Andalusia will be the same as in the rest of Spain and we interpret that the recent modification of the Andalusian Pharmacy Law remains a dead letter."

EMA Recommended 97 New Meds in 2020, According to Highlights Report

Date: January 25, 2021 | Country: BELGIUM, NETHERLANDS | Region: EU27, EU27 + UK, EUROPE | Type: Drug Approval | Keywords: #agency #approval #atmp #biosimilar #cell #commission #covid-19 #drug #european #gene #medicines #recommendation

PRICENTRIC BRIEF:

- The European Medicines Agency's (EMA) newly-released "Human Medicines: Highlights 2020" report shows that in 2020, the European Union (EU) drug regulator issued 97 positive opinions for new medicines, a substantial increase of 31 on the previous year, despite the pandemic
- Of the 91 approvals, 39 contained a new active substance that had never been authorized in the EU until now, and 12 were biosimilar versions of already-approved drugs
- In a year unlike any other, unpredictable conditional marketing authorizations were also issued for Gilead's Veklury (remdesivir) for COVID-19 treatment in June, as well as for Comirnaty later in the year, the COVID-19 vaccine co-developed by Pfizer and BioNTech

THE DETAILS

AMSTERDAM, The Netherlands – The European Medicines Agency's (EMA) newly-released "Human Medicines: Highlights 2020" report shows that in 2020, the European Union (EU) drug regulator issued 97 positive opinions for new medicines, a substantial increase of 31 on the previous year, despite the pandemic.

Of the 91 approvals, 39 contained a new active substance that had never been authorized in the EU until now, and 12 were biosimilar versions of already-approved drugs.

Gene Therapies

2020 was a big year for cell and gene therapies, and the EMA recommended three – Novartis' Zolgensma (onasemnogene abeparvovec), Kite's Tecartus (autologous anti-CD19 transduced CD3+ cells) and Orchard's lentiviral vector-based Libmeldy (autologous CD34+ cells encoding the ARSA gene) - for approval.

Referred to in the report as advanced therapy medicinal products (ATMPs), the three pivotal recommendations surpass the one recommendation that was made for a gene therapy the previous year – as bluebird bio's Zynteglo (betibeglogene autotemcel) was the only drug of its kind to make the cut in 2019's report.

COVID-19

In a year unlike any other, unpredictable conditional marketing authorizations were issued for Gilead's Veklury (remdesivir) for COVID-19 treatment in June, as well as for Comirnaty later in the year, the COVID-19 vaccine co-developed by Pfizer and BioNTech.

Both conditional marketing authorizations included obligations for the companies to fulfill; Pfizer was asked to continue to provide results from the ongoing clinical trial as well as carrying out studies to provide additional assurance on the pharmaceutical quality of the vaccine as the manufacturing continues to be scaled up.

Gilead already satisfied its promise and provided the EMA with more data on the quality, effectiveness and safety of the medicine and the final reports of studies with Veklury before the end of 2020.

Since the cut-off point of the report, the EMA has also recommended granting conditional marketing authorization for COVID-19 Vaccine Moderna for

the prevention of Coronavirus disease (COVID-19) in people aged 18 years and up.

PRIME Scheme

The report also notes that over the course of 2020, eight meds were recommended for approval under the EMA's Priority Medicines Scheme (PRIME):

- Blenrep (belantamab mafodotin)
- Rozlytrek (entrectinib)
- Tecartus
- Givlaari (givosiran)
- Hepcludex (bulevertide)
- Zolgensma
- Idefirix (imlifidase)
- Oxlumo (lumasiran)

Orphan Meds

Among the 97 medicines recommended for marketing authorization in 2020, 22 had their orphan designation confirmed by the end of the year, ready to be reviewed by the Committee for Orphan Medicinal Products (COMP).

Designations of note included Elzonris (tagraxofusp), Libmeldy, Hepcludex and Oxlumo, as they all provide a new treatment option for an indication that doesn't have any approved products so far.

The Orphan Drug Legislation is currently under re-evaluation after the European Commission released a document analyzing the benefits and outputs of the scheme.

The Commission's release, which notes both the positive outcomes and the shortcomings of the legislation, concludes that for the most part, the orphan regulation has had a positive impact by adding 210,000-440,000 quality-adjusted life years for patients in the EU, despite increasing costs by €23 billion from 2000-2017.

On the release of the report, the Regulatory Affairs Professionals Society (RAPS) reminds that 142 orphan medicines have been authorized in the EU since 2000, 131 of which are still on the market.

Before the release of the document, critics had already suggested that re-opening the Legislation may prove to be risky for both the pharma industry and patients, with the European Federation of Pharmaceutical Industries and Associations (EFPIA) previously stating that "we need to further incentivize the research and development of new treatments for patients where, currently, no treatment options exist."

Rejections

The EMA's Committee for Medical Products for Human Use (CHMP) did, however, issue two negative opinions over the course of 2020.

Sobi's Gamifant (emapalumab) as a treatment for primary haemophagocytic lymphohistiocytosis (HLH) was given a final rejection after the Committee initially turned away the drug in July, due to an "unconvincing" study.

It also voted against Daiichi Sankyo's Turalio (pexidartinib), which was to be used to treat tenosynovial giant cell tumors, citing concern for small improvement in clinical outcomes and uncertainty about the duration of effect, as well as potentially life-threatening adverse effects.

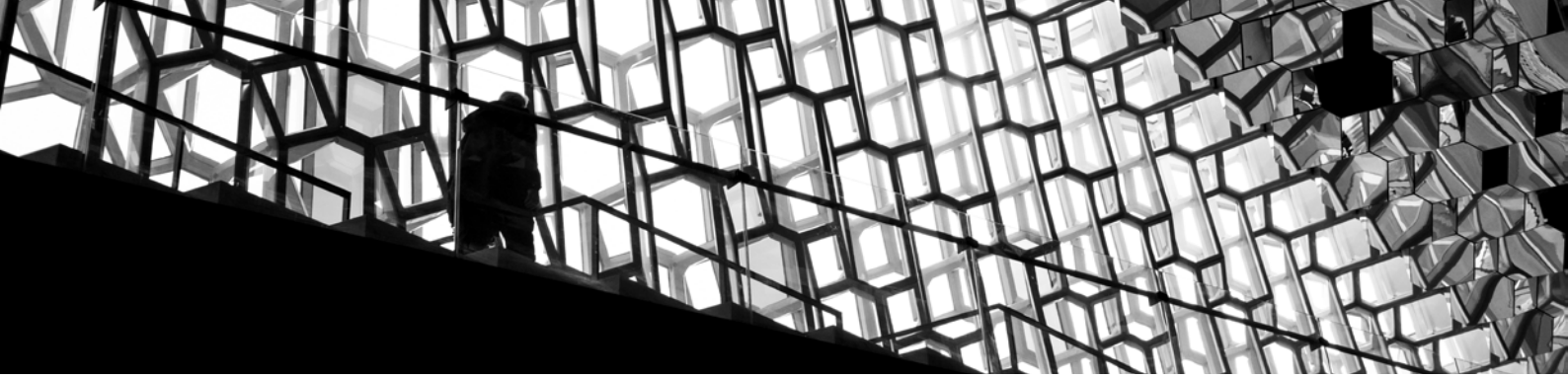
The Future of Access

In December the EMA also published a joint strategy on medicine availability and access with the Heads of Medicines Agencies (HMA) for the next five years, in which the groups highlight six priority areas, including specific goals that will be translated into "concrete actions" over the next five years.

According to Emer Cooke, EMA's Executive Director, "The COVID-19 pandemic has highlighted the pivotal role of medicine regulation for the protection of public health. Lack of availability of medicines, either because they are not marketed or due to supply disruptions, has shown to pose serious threats to patient and animal health, animal disease control programs and sustainable livestock production. This strategy ensures that we join forces across the EU to effect tangible improvements for citizens."

Their strategy discusses how these regulators will enable the supply of safe and effective medicines that meet patients' needs considering the "ever-accelerating developments" in science, medicine, digital technologies, globalization, and emerging health threats like the COVID-19 pandemic.

The network will review its strategy after 18 months to gauge its feasibility and efficacy and will make adjustments if necessary.



Drug Access Protocol Promises to Bring Oncology Drugs to Dutch Patients Faster

Date: January 22, 2021 | Country: NETHERLANDS | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #access #cancer #negotiation #netherlands #oncology #patient #reimbursement #scheme

PRICENTRIC BRIEF:

- A new project, dubbed Drug Access Protocol (DAP), has been launched in the Netherlands with the potential to expedite access to oncology drugs for those in need in the Netherlands
- The scheme, which was put together by Dutch oncologists, insurers and Zorginstituut (ZIN), will introduce patient access schemes – similar to that of the UK's Cancer Drugs Fund (CDF) - that will allow patients to access new oncology drugs while they are still under reimbursement negotiations with the relevant company
- The Innovative Medicines Association (VIG) of the Netherlands looked to the German model for inspiration, commenting how, "In Germany, all medicines are immediately available to patients after EMA registration. Negotiations about the price only start afterwards, when more and more data about the effect of that drug becomes available. We can learn something from that."

THE DETAILS

AMSTERDAM, The Netherlands – A new project, dubbed Drug Access Protocol (DAP), has been launched in the Netherlands with the potential to expedite access to oncology drugs for those in need in the Netherlands.

The scheme, which was put together by Dutch oncologists, insurers and Zorginstituut (ZIN), will introduce patient access schemes – similar to that of the UK's Cancer Drugs Fund (CDF) - that will allow patients to access new oncology drugs while they are still under reimbursement negotiations with the relevant company.

The risk-sharing method holds organizations more accountable, as they won't get paid if the treatment doesn't work.

The Innovative Medicines Association (VIG) of the Netherlands looked to the German model for inspiration, commenting how, "In Germany, all medicines are immediately available to patients after EMA registration. Negotiations about the price only start afterwards, when more and more data about the effect of that drug becomes available. We can learn something from that."

The access scheme is part of the Netherlands' ongoing overhaul of its oncology landscape. At the end of last year, the Medicines Association (VIG) of the Netherlands supported the notion that the country's Minister Van Ark, of Medical Care, promised to work on faster access to new and life-saving medicines, having taken into account recent findings on accessibility issues in the country.

A variety of cancer treatments have already been agreed under the system, including Sanofi's Libtayo (cemiplimab).

EUCope Calls for 'Coherent Approach', RWE Use in ATMP Funding Paper

Date: January 21, 2021 | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #althernative #atmps #cell #eucope #gene #payment #pricing #therapy

PRICENTRIC BRIEF:

- EUCope, a trade body for small to medium-sized innovative pharma companies, has published a new "Position Paper on New Payment & Funding Approaches for ATMPs"
- Taking into stock the issues that mar newer, innovative drugs in their market access pathway, the paper ultimately calls for a "new paradigm of care, where it is necessary to consider the affordability issues for health systems, from a long-term perspective"
- Options such as RWE-collection, outcome-based models and annuity payments are being increasingly discussed in order to help mitigate affordability issues and get patients the fastest access to ATMPs across Europe

THE DETAILS

BRUSSELS, Belgium – EUCope, a trade body for small to medium-sized innovative pharma companies, has published a new "Position Paper on New Payment & Funding Approaches for ATMPs."

Taking into stock the issues that mar newer, innovative drugs in their market access pathway, the paper ultimately calls for a "new paradigm of care, where it is necessary to consider the affordability issues for health systems, from a long-term perspective."

It goes on to explain how a coherent approach with the scientific community could benefit healthcare systems, as well as increased use of real-world evidence (RWE) and potentially specific ATMP funds.

The paper explains how "A collaborative approach to innovative payments models such as outcome-based agreements and new funding schemes may play a crucial role in alleviating challenges on the uncertainties of data and affordability and ensuring payers have the confidence to invest in one-time treatments, enabling patients to benefit from effective ATMPs, and position Europe as an attractive research leader."

As more advanced therapy medicinal products (ATMPs) are coming through pipelines, alternative payment and reimbursement methods have been increasingly discussed in various countries throughout Europe.

Recently, Sweden's TLV announced a webinar on developing health economic assessments for precision medicines and investigating possible payment models for gene and cell therapies (ATMPs).

Options such as RWE-collection, outcome-based models and annuity payments are being debated more and more in order to help mitigate affordability issues and get patients the fastest access to ATMPs across Europe.

Germany's GKV-SV Criticizes Health App Reimbursement

Date: January 18, 2021 | Country: GERMANY | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #diga #digitaltherapeutics #economicevaluation #fixedprices #gkvsv #healthapps #hta #policy #priceincreases #regulation

PRICENTRIC BRIEF:

- It's been three months since Germany first started reimbursing digital health applications (DiGA), and now the legal framework for their approval and reimbursement has come under fire in a recent position paper from Germany's umbrella payer GKV-Spitzenverband (GKV-SV)
- GKV-SV is calling for apps to be compared to other apps, not non-use, and for economic efficiency evaluations as well as the establishment of maximum amounts for these apps beginning from day one of reimbursement
- As reported by ArtzeZeitung, stakeholders are currently amid a dispute over fixing maximum amounts for apps, with a second hearing set for January 26, 2020

THE DETAILS

BERLIN, Germany – It's been three months since Germany first started reimbursing digital health applications (DiGA), and now the legal framework for their approval and reimbursement has come under fire in a recent position paper from Germany's umbrella payer GKV-Spitzenverband (GKV-SV).

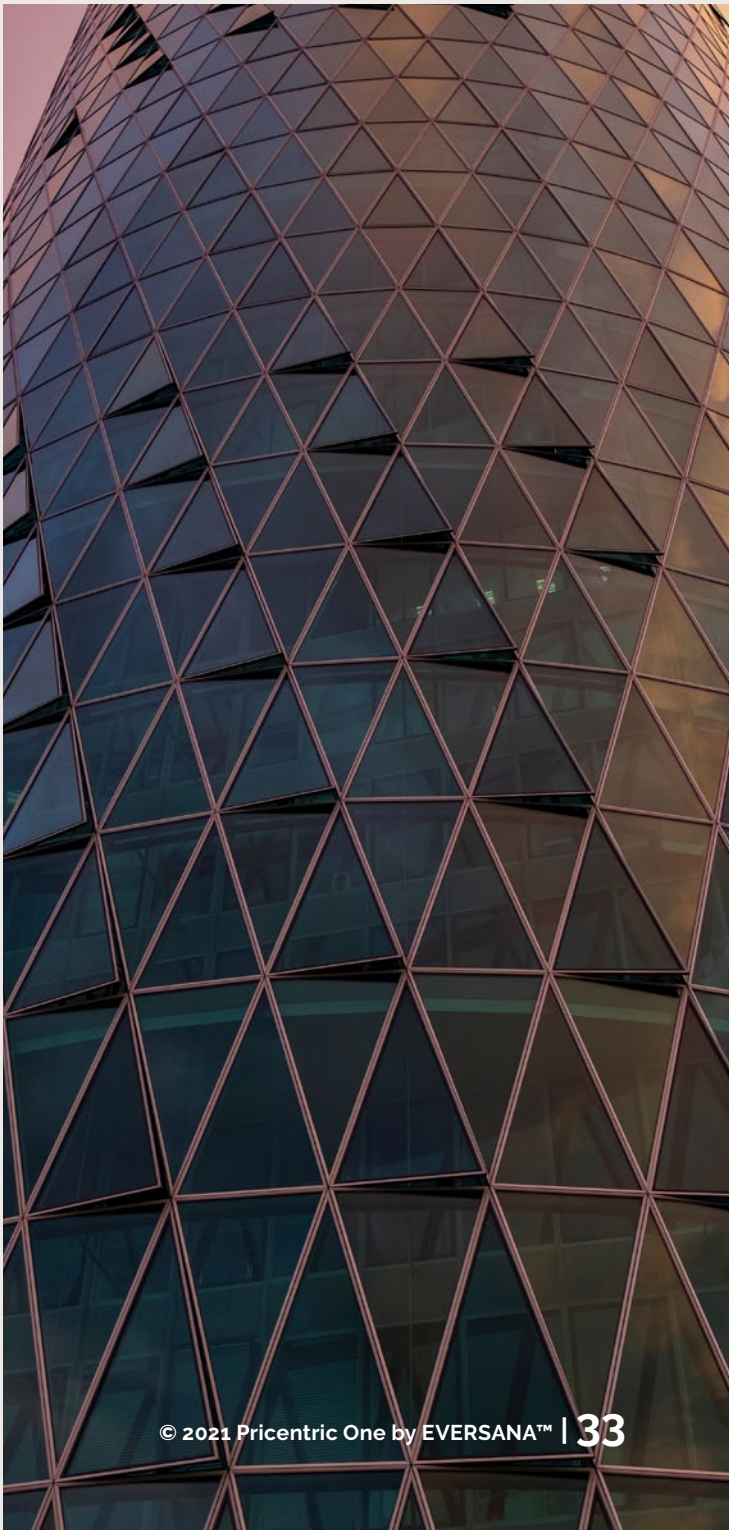
For GKV-SV, the framework for DiGA approval and reimbursement is "inadequately designed," the payer adding that "a patient-relevant structural and procedural improvement alone should…not constitute a sufficient condition for reimbursement."

The core requirement for the reimbursement of a DiGA should be its medical benefit for the insured person, and the app must provide equally as high – or higher benefit – compared to other apps, not in comparison to not using an app.

The payer also raised concerns with the fast-track procedure for health apps, backing instead the use of economic efficiency, as current practice seemingly undermines quality standards for these apps.

As with medical products, apps in Germany enjoy one year of free pricing while their level of benefit is assessed. However, according to GKV-SV, price increases of upwards of 500% in some cases have been noted for DiGAs.

The payer is calling for a maximum price to be fixed for the apps, set the first day of reimbursement, even though manufacturers are opposed to such limitations. As reported by ArtzeZeitung, stakeholders are currently amid a dispute over fixing maximum amounts for apps, with a second hearing set for January 26, 2020. However, the negotiations haven't been made public.



Fimea Publishes Evaluation of Alexion's Soliris, Eyes Alternative Pricing Model

Date: January 15, 2021 | Country: FINLAND | Region: EUROPE | Type: HTA | Keywords: #disorder #eculizumab #fimea #neuromyelitis #optica #soliris

PRICENTRIC BRIEF:

- The Finnish Medicines Agency (Fimea) has published its evaluation of the therapeutic and economic effects of Alexion's Soliris (eculizumab) neuromyelitis optica disorder (NMOSD)
- Fimea's assessment was based on the placebo-controlled PREVENT study, in which treatment with Soliris was shown to have some benefit in reducing the number of NMOSD relapses
- As the treatment is unusually expensive, the Ministry of Social Affairs and Health (MAH) has proposed an alternative pricing model to ensure access, but the details of the arrangement have not been disclosed

THE DETAILS

HELSINKI, Finland - The Finnish Medicines Agency (Fimea) has published its evaluation of the therapeutic and economic effects of Alexion's Soliris (eculizumab) neuromyelitis optica disorder (NMOSD).

Soliris is currently the only authorized medicinal product for the treatment of NMOSD in Europe, after it was granted a marketing authorization for the indication in 2019.

Fimea's assessment was based on the placebo-controlled PREVENT study, in which treatment with Soliris was shown to have some benefit in reducing the number of NMOSD relapses.

However, the group noted that the actual level of the benefit is somewhat unclear, as the number of relapses also decreased significantly in the placebo group.

As the treatment is unusually expensive, the Ministry of Social Affairs and Health (MAH) has proposed an alternative pricing model to ensure access, but the details of the arrangement have not been disclosed.

ViiV, Chelsea & Westminster NHS Trusts Roll Out Digital Management Tool, Klick

Date: January 19, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Type: Regulation | Keywords: #collaboration digitaltherapeutics #healthapp #hiv #jointworkingagreement #klick #kobleroutpatientclinic #nhstrust #viiv

PRICENTRIC BRIEF:

- The partnership between ViiV Healthcare and Chelsea and Westminster Hospital NHS Foundation Trust has announced the launch of Klick, a new service created under a joint working agreement that leverages digital technology to provide patients improved access to care
- Supported by a mobile app, Klick allows patients to perform a slew of necessary tasks related to their health, including manage appointments, complete health assessments, review results, and remain in contact with their healthcare team
- At first, Klick is launching at the Kobler Outpatient Clinic, before it is expanded across NHS trusts in the coming months

THE DETAILS

LONDON, United Kingdom – The partnership between ViiV Healthcare and Chelsea and Westminster Hospital NHS Foundation Trust has announced the launch of Klick, a new service created under a joint working agreement that leverages digital technology to provide patients improved access to care.

Supported by a mobile app, Klick allows patients to perform a slew of necessary tasks related to their health, including manage appointments, complete health assessments, review results, and remain in contact with their healthcare team.

The pilot program for Klick received positive feedback, prompting the formation of a Joint Working Agreement to pursue the manifestation of the digital tool. At first, Klick is launching at the Kobler Outpatient Clinic, before it is expanded across NHS trusts in the coming months.

Dr. Thomas Van Every, Global Medical Affairs Director at ViiV Healthcare, commented, "All too often, innovations in healthcare fail when placed into the complex environment of a health system. ViiV Healthcare's innovation specialists design solutions which leverage technology but are also rooted in the science of implementation. This demonstrates our commitment to understanding the drivers and barriers to implementing innovations in real-world settings. Our partnership with Chelsea and Westminster Hospital NHS Foundation Trust has combined experience in innovation with delivering quality care to patients within the NHS. The output is a robustly tested service for HIV patients, designed to be fit for the future of HIV care."

Dr. David Asboe, Clinical Director for HIV at Chelsea and Westminster Hospital NHS Foundation Trust, said, "We have made significant advances in the care of people living with HIV, but this work is not finished. In many regards, it has just begun. Our combined efforts have shifted HIV from an acute to a predominantly long-term condition. This brings its own challenges and responsibilities. It is our duty to understand the emerging needs of our patient cohort, to design care that is responsive to these needs, and to provide care in a sustainable fashion. We must achieve these things with a backdrop of the challenges we now also face with COVID-19.

Health systems are under more pressure than ever and using new technologies in a way that genuinely enables our services to evolve is absolutely critical to ensuring we can continue to improve how we deliver quality care to our patients. The collaboration between the Trust and ViiV Healthcare has provided an opportunity to produce an evidence-based and practical service concept that provides a strong platform on which we can build."

COVID-19 Vaccine Highlights

EMA Recommends Conditional Marketing Authorization for COVID-19 Vaccine Moderna

Date: January 6, 2021 | Country: NETHERLANDS | Region: EU27 + UK, EU28, EUROPE | Type: Drug Approval | Keywords: # chmp #conditionalmarketing #covid19 #ema #europeancommission #moderna #vaccine

PRICENTRIC BRIEF:

- The European Medicines Agency (EMA) has recommended granting conditional marketing authorization for COVID-19 Vaccine Moderna for the prevention of Coronavirus disease (COVID-19) in people aged 18 years and up
- Clinical trial evidence shows the COVID-19 Vaccine Moderna was effective in preventing COVID-19 in people aged 18 years and older, the vaccine demonstrating a 94.1% efficacy rate
- This is the second COVID-19 vaccine EMA has recommended for approval, following Pfizer and BioNTech's Comirnaty, or BNT162b2, for active immunization to prevent COVID-19 caused by SARS-CoV-2 in patients aged 16 years and older

Moderna Gets European Commission Go-ahead for COVID-19 Vaccine

Date: January 7, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Keywords: #authorization #commission #covid-19 #emergency #european #moderna #pfizer #use #vaccine

PRICENTRIC BRIEF:

- The European Commission has granted a conditional marketing authorization (CMA) to Moderna's COVID-19 vaccine, marking the second time a COVID-19 vaccine has been authorized in the European Union
- The official authorization follows a recommendation from the European Medicines Agency (EMA) based on clinical trial evidence that showed Moderna's vaccine effort was effective in preventing COVID-19 in people aged 18 years and older
- Following the approval, Moderna will deliver the total amount of 160 million doses between the first and the third quarters of 2021, adding to the already-rolling out 300 million doses of Pfizer's vaccine in the EU

UK's MHRA Approves Moderna's COVID-19 Vaccine, Eyes 10M Additional Doses to Roll-out From Spring

Date: January 8, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Type: Drug Approval | Keywords: #approval #biontech #covid-19 #mhra #moderna #mrna #pfizer #sars #uk #vaccine

PRICENTRIC BRIEF:

- The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has approved its third COVID-19 vaccine for use, Moderna's messenger RNA (mRNA) shot
- The government is also looking to order an additional 10 million doses, bringing the total pre-purchase amount to 17 million from Moderna, so that the vaccine can ideally be rolled out from March
- The vaccine will join the ranks of the Pfizer/BioNTech and AstraZeneca (AZ) jabs, which have both already been approved by the UK drug regulator

EC President Warns Member States Against Purchasing COVID-19 Vaccines Individually

Date: January 11, 2021 | Country: BELGIUM,

FRANCE, GERMANY, ITALY, SPAIN | Region: EU14 + UK, EU15, EU27 + UK, EU28, EUROPE | Type: Pricing & Reimbursement | Keywords: #bloc #commission #covid-19 #european #member #procurement #states #tender #vaccine

PRICENTRIC BRIEF

- European Commission President, Ursula von der Leyen, has urged individual European Union member states to refrain from arranging their own COVID-19 vaccine purchases outside the EU-led procurement
- Speaking in Brussels, the President explained: "The only framework we are negotiating in is as 27, we do this together, and no member state on this legal binding basis is allowed to negotiate in parallel or to have a contract in parallel"
- The Commission has negotiated a total of 2.3 billion doses of vaccine from various pharmaceutical companies, and two safe and effective vaccines against the virus have been authorized for use in the EU following positive scientific recommendations by the European Medicines Agency (EMA) – Pfizer/Bio'N'tech and Moderna's efforts

Europe, Valneva Amid Discussions for 60 M Doses of VLA2001

Date: January 12, 2021 | Country: BELGIUM, UNITED KINGDOM | Region: EU27 + UK, EU28, EUROPE | Type: Regulation | Keywords: #clinicaltrials #covid19 #europeacommission #vaccine #valneva #vla2001

PRICENTRIC BRIEF:

- Valneva is amid advanced discussions with the European Commission for the supply of up to 60 million doses of the French-based company's COVID-19 vaccine, VLA2001, the only inactivated vaccine candidate in clinical trials against COVID-19 in Europe
- The company expects to report on safety and immunogenicity data in April of this year and then move forward with the second part of the Phase 1/2 clinical development—as such, initial approval of VAL2001 is anticipated in the second half (H2) of 2021
- Already, the company has a deal in place with the United Kingdom for up to 190 million doses of its inactivated vaccine, under which 60 million doses of the vaccine will be provided to the government in H2 2021 if vaccine development is successful

AstraZeneca Submits CMA to EMA for COVID-19 Vaccine

Date: January 12, 2021 | Country: BELGIUM, NETHERLANDS | Region: EUROPE | Type: Regulation | Keywords: #astrazeneca #cma #commission #coronavirus #covid #vaccine

PRICENTRIC BRIEF:

- The European Medicines Agency (EMA) has announced the receipt of AstraZeneca's conditional marketing authorization (CMA) for its COVID-19 vaccination
- The vaccine, which has been jointly developed by AstraZeneca and Oxford University, will now undergo an accelerated approval process with an end goal of 29 January, 2021
- The CMA submission sets the ball rolling for the European Commission to approve its third COVID-19 vaccine for use, following Pfizer and BioNTech's shot and Moderna's effort

U.S Rejoins WHO, Joins COVAX as Pfizer/BioNTech Agree to Supply Scheme

Date: January 22, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy | Keywords: #biden #biontech #comirnaty #covax #joe #pfizer #us #who

PRICENTRIC BRIEF:

- Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, has announced that under the newly-instated Biden administration the U.S. is set to join COVAX
- In a speech to WHO, the lead doctor also noted: "I am honored to announce the US will remain a member of the WHO. The US also intends to fulfil its financial obligations to the organization"
- The announcements come amid news that Pfizer and BioNTech have agreed to supply their COVID-19 vaccine, Comirnaty, to COVAX, according to sources interviewed by Reuters

COVID-19 Vaccine Tracker

Company	Vaccine	Technology	Trial Phase	Efficacy	Price	U.S. Deals
Moderna & National Institutes of Health	mRNA-1273	mRNA	3	94.5%	$25-$37 [1]	$4.1 billion
Pfizer & BioNTech	BNT162b2	mRNA	Combined 2 and 3	95%	$20 [2]	$1.9 billion
CureVac	CVnCoV	mRNA	3	encouraging response	-	-
CanSino Biologics & Military	Ad5-nCoV	viral vector	3	encouraging response	-	-
J & J & Beth Israel	Ad26.COV2.S	viral vector	3	72%	~ $10 [3]	$1 billion
Gamaleya Research Institute	Gam-Covid-Vac (Sputnik V)	viral vector	3	91.4%	-	-
AstraZeneca & U Oxford	AZD1222	viral vector	combined 2 and 3	up to 90%	~ $3 to $4 [4]	$1.2 billion
Novavax	NVX-CoV2373	protein based	3	encouraging response	$16 [5]	expects to deliver 100 million doses in U.S.
Medicago & GSK	CoVLP	protein based	combined 2 and 3	encouraging response	-	-
Sanofi & GSK	-	protein based	Combined 1 and 2	not as effective as hoped	$11.80 [6]	$2.1 million
Wuhan Institute & Sinopharm	-	attenuated coronavirus	3	encouraging response	$145 for two shots [7]	-
Sinovac	CoronaVac	attenuated coronavirus	3	50.38%	$29.75 [8]	-

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

[1] https://indianexpress.com/article/coronavirus/moderna-covid-19-vaccine-cost-7060816/ [2] https://www.cnbc.com/2020/11/17/covid-vaccines-how-much-they-cost-whos-bought-them-and-how-theyre-stored.html [3] https://www.cnbc.com/2020/11/17/covid-vaccines-how-much-they-cost-whos-bought-them-and-how-theyre-stored.html [4] https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686 [5] https://observer.com/2020/08/covid19-vaccine-price-comparison-moderna-pfizer-novavax-johnson-astrazeneca/ [6] www.reuters.com/article/us-health-coronavirus-sanofi/sanofi-france-chief-sees-coronavirus-vaccine-priced-below-10-euros-idUSKBN25W0EU [7] https://www.scmp.com/news/china/science/article/3098032/coronavirus-chinese-vaccine-giant-quotes-higher-price-doses [8] https://www.reuters.com/article/us-health-coronavirus-china-vaccine/sinovac-coronavirus-vaccine-offered-by-chinese-city-for-emergency-use-costs-60-idUSKBN2710UQ#:~:text=The%20eastern%20city%20of%20Jiaxing's,including%20medical%20professionals%20have%20begun.

HTA Decisions: France

- HAS/TC in France has conducted an assessment of Pemetrexed (Pemetrexed; Ever Pharma) for Nsclc (previously Treated). Result: The actual benefit of Pemetrexed EVER Pharma (25 mg / ml) is substantial in the indications of the marketing authorization.
- HAS/TC in France has conducted an assessment of Pemetrexed (Pemetrexed; Ever Pharma) for Malignant Pleural Mesothelioma. Result: The actual benefit of Pemetrexed EVER Pharma (25 mg / ml) is substantial in the indications of the marketing authorization.
- HAS/TC in France has conducted an assessment of Asterluna Continu (Levonorgestrel + Ethinylestradiol; Exeltis) for Oral Contraception. Result: The actual benefit of ASTERLUNA CONTINU (levonorgestrel / ethinylestradiol) is substantial in the indication in the marketing authorization.
- HAS/TC in France has conducted an assessment of Xylocard (Lidocaine; Aspen) for Anesthesia. Result: The actual benefit of XYLOCARD 20 mg / ml intravenous (Lidocaine hydrochloride) is substantial in the new indication in the Marketing Authorization.
- HAS/TC in France has conducted an assessment of Pemetrexed (Pemetrexed; Ever Pharma) for Nsclc (cisplatin). Result: The actual benefit of Pemetrexed EVER Pharma (25 mg / ml) is substantial in the indications of the marketing authorization.
- HAS/TC in France has conducted an assessment of Mabthera (Rituximab; Roche) for Diffuse Large B-cell Non-hodgkin Lymphoma (chop). Result: The actual benefit of MABTHERA (rituximab) in combination with chemotherapy is important in the treatment of previously untreated pediatric patients (aged 6 months to <18 years) with advanced stage: diffuse large B-cell lymphoma (LDGCB) CD20 positive, Burkitt lymphoma (LB) / Burkitt leukemia (acute mature B cell leukemia) (LA-B) or Burkitt-like lymphoma (LB-like).
- HAS/TC in France has conducted an assessment of Gamunex (Immunoglobulins, Normal Human, For Intravascular Adm.; Grifols) for Primary Immunodeficiency Syndromes. Result: The actual benefit of GAMUNEX (Human normal immunoglobulin) is significant in the new indication in the Marketing Authorization, namely the treatment of severe acute myasthenic attacks.
- HAS/TC in France has conducted an assessment of Mabthera (Rituximab; Roche) for Non-hodgkin Lymphoma (combination). Result: The actual benefit of MABTHERA (rituximab) in combination with chemotherapy is important in the treatment of previously untreated pediatric patients (aged 6 months to <18 years) with advanced stage: diffuse large B-cell lymphoma (LDGCB) CD20 positive, Burkitt lymphoma (LB) / Burkitt leukemia (acute mature B cell leukemia) (LA-B) or Burkitt-like lymphoma (LB-like).
- HAS/TC in France has conducted an assessment of Pemetrexed (Pemetrexed; Ever Pharma) for Nsclc (previously Treated). Result: The actual benefit of Pemetrexed EVER Pharma (25 mg / ml) is substantial in the indications of the marketing authorization.
- HAS/TC in France has conducted an assessment of Mabthera (Rituximab; Roche) for Diffuse Large B-cell Non-hodgkin Lymphoma (chop). Result: The actual benefit of MABTHERA (rituximab) in combination with chemotherapy is important in the treatment of previously untreated pediatric patients (aged 6 months to <18 years) with advanced stage: diffuse large B-cell lymphoma (LDGCB) CD20 positive, Burkitt lymphoma (LB) / Burkitt leukemia (acute mature B cell leukemia) (LA-B) or Burkitt-like lymphoma (LB-like).

HTA Decisions: Germany

- G-BA in Germany has conducted an assessment of Zeposia (Ozanimod; Celgene) for Multiple Sclerosis. Result: Indication of minor additional benefit
- G-BA in Germany has conducted an assessment of Cablivi (Caplacizumab; Sanofi) for Thrombotic Thrombocytopenic Purpura. Result: There is no indication of a non-quantifiable additional benefit because the scientific data basis does not allow quantification.
- G-BA in Germany has conducted an assessment of Isturisa (Osilodrostat; Recordati) for Cushing's Syndrome. Result: For osilodrostat for the treatment of endogenous Cushing's syndrome in adults, there is a hint of a non-quantifiable added benefit.
- G-BA in Germany has conducted an assessment of Zeposia (Ozanimod; Celgene) for Multiple Sclerosis. Result: For patients who still show high disease activity despite previous treatment, the appropriate comparative therapy determined by the G-BA of escalation to a more active therapy (alemtuzumab, fingolimod or natalizumab) has not been implemented. There are therefore no suitable data compared to the ACT for these patients. An added benefit is therefore not proven.
- IQWiG in Germany has conducted an assessment of Epidyolex (Cannabidiol; Gw Pharmaceuticals) for Dravet Syndrome. Result: The additional benefit of an orphan drug is considered proven by the approval. For this reason, the assessment of the added benefit is not the subject of this report.
- IQWiG in Germany has conducted an assessment of Epidyolex (Cannabidiol; Gw Pharmaceuticals) for Seizures (lennox-gastaut Syndrome). Result: The additional benefit of an orphan drug is considered proven by the approval. For this reason, the assessment of the added benefit is not the subject of this report.
- IQWiG in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: There was no statistically significant difference for the outcome "all-cause mortality" between treatment groups. This gives no clue for an added benefit of filgotinib + MTX in comparison with adalimumab + MTX.
- IQWiG in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: There are prognostic factors that do not adequately respond to previous treatment with csDMARD or did not tolerate it. No data to evaluate the added benefit of filgotinib in comparison with the ACT. There was no hint of an added benefit of filgotinib compared to the appropriate comparator therapy.
- IQWiG in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: For the assessment of the added benefit of filgotinib in adult patients who have inadequately responded to a previous treatment with 1 or more bDMARDs and / or tsDMARDs or did not tolerate them, the company sets out no data. So, an added benefit of filgotinib compared to the appropriate comparative therapy has not been proven for these patients.
- IQWiG in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: There was no statistically significant difference for the outcome "all-cause mortality" between treatment groups. This gives no clue for an added benefit of filgotinib + MTX in comparison with adalimumab + MTX.

HTA Decisions: Germany (cont.)

- IQWiG in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: For the assessment of the added benefit of filgotinib in adult patients who have inadequately responded to a previous treatment with 1 or more bDMARDs and / or tsDMARDs or did not tolerate them, the company sets out no data. So, an added benefit of filgotinib compared to the appropriate comparative therapy has not been proven for these patients
- IQWiG in Germany has conducted an assessment of Jyseleca (Filgotinib; Gilead Sciences Inc) for Rheumatoid Arthritis. Result: There are prognostic factors that do not adequately respond to previous treatment with csDMARD or did not tolerate it. No data to evaluate the added benefit of filgotinib in comparison with the ACT. There was no hint of an added benefit of filgotinib compared to the appropriate comparator therapy.

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Drug Approvals: United States

- XALKORI (CRIZOTINIB) was approved by the FDA for pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive.
COMPANY: PFIZER

- NOREPINEPHRINE BITARTRATE IN DEXTROSE (NOREPINEPHRINE BITARTRATE AND DEXTROSE) was approved by the FDA for restoration of blood pressure in adult patients with acute hypotensive states.
COMPANY: BAXTER HLTHCARE CORP

- DARZALEX FASPRO (DARATUMUMAB & HYALURONIDASE-FIHJ) was approved by the FDA in combination with bortezomib, cyclophosphamide and dexamethasone for newly diagnosed light chain (AL) amyloidosis.
COMPANY: JANSSEN

- ENHERTU (FAM-TRASTUZUMAB DERUXTECAN-NXKI) was approved by the FDA for adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen.
COMPANY: DAIICHI SANKYO

- ACETAMINOPHEN (ACETAMINOPHEN) was approved by the FDA for the • Management of mild to moderate pain in adult and pediatric patients 2 years and older • Management of moderate to severe pain with adjunctive opioid analgesics in adult and pediatric patients 2 years and older • Reduction of fever in adult and pediatric patients.
COMPANY: MYLAN LABS LTD

- VERQUVO (VERICIGUAT) was approved by the FDA to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.
COMPANY: MERCK SHARP DOHME

- CABENUVA (CABOTEGRAVIR AND RILPIVIRINE) was approved by the FDA for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults.
COMPANY: JANSSEN

- VOCABRIA (CABOTEGRAVIR) was approved by the FDA as a complete regimen for the treatment of HIV-1 infection in adults to replace their current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.
COMPANY: VIIV HLTHCARE

- OPDIVO (NIVOLUMAB) was approved by the FDA as first-line treatment for patients with advanced renal cell carcinoma (RCC).
COMPANY: BRISTOL-MYERS SQUIBB

Drug Approvals: EMA

- COVID-19 VACCINE MODERNA (COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)) was approved by the EMA for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older.
  COMPANY: MODERNA
- ROCLANDA (LATANOPROST & NETARSUDIL) was approved by the EMA for reducing pressure inside the eye in adults who have open-angle glaucoma or ocular hypertension. It is for patients in whom treatment with either a prostaglandin medicine or netarsudil alone did not sufficiently reduce the pressure.
  COMPANY: AERIE
- XOFLUZA (BALOXAVIR MARBOXIL) was approved by the EMA for treating and preventing flu in adults and children from 12 years of age.
  COMPANY: ROCHE

Germany: Post-AMNOG Price Changes for Originator Drugs

Company	Product Group	Generic Name	Description	MNF (Euro)	OLD MNF	Change	%Change
PFIZER	BOSULIF	BOSUTINIB	BOSULIF TABLETS 1 PACK 112 TABS 100 MG	2004.80	2238.43	-233.63	-10.44%
PFIZER	BOSULIF	BOSUTINIB	BOSULIF TABLETS 1 PACK 28 TABS 100 MG	501.20	559.61	-58.41	-10.44%
PFIZER	BOSULIF	BOSUTINIB	BOSULIF TABLETS 1 PACK 28 TABS 400 MG	2004.80	2238.43	-233.63	-10.44%
PFIZER	BOSULIF	BOSUTINIB	BOSULIF TABLETS 1 PACK 28 TABS 500 MG	2506.00	2798.04	-292.04	-10.44%
ASTRAZENECA	BRIMICA GENUAIR	FORMOTEROL & ACLID BRO	BRIMICA GENUAIR PWDR 1 INHAL 60 D 352 MCG	49.73	51.00	-1.27	-2.49%
ASTRAZENECA	BRIMICA GENUAIR	FORMOTEROL & ACLID BRO	BRIMICA GENUAIR PWDR 3 INHAL 60 D 352 MCG	149.18	153.00	-3.82	-2.50%

Drug Launches: Europe & US

Country	Generic Name	Product Group	Company	Indication	Approval Date	Launch Date
GERMANY	VILANTEROL & UMECLID BROM	ANORO ELLIPTA	GLAXOSMITHKLINE	COPD	08/05/2014	15/01/2021
GERMANY	LUMASIRAN	OXLUMO	ALNYLAM	PRIM HYPEROXALURIA TYPE 1 (PH1)	19/11/2020	01/01/2021
ITALY	INFLU, INACT, SPLIT / SURF ANTIG	FLUAD TETRA	SEQIRUS	PREVENTION OF INFLUENZA	20/05/2020	19/01/2021
ITALY	VORETIGENE NEPARVOVEC	LUXTURNA	NOVARTIS	LEBER'S CONGEN AMAUROSIS (RPE65)	22/11/2018	09/01/2021
SPAIN	BUROSUMAB	CRYSVITA	KYOWA CHEMICALS	HYPOPHOSPHATEM (X-LINKED-PED)	19/02/2018	01/01/2021
UNITED STATES	REMIMAZOLAM	BYFAVO	ACACIA PHARMA	SEDATION	02/07/2020	01/01/2021
UNITED STATES	VIBEGRON	GEMTESA	UROVANT SCIENCES	OVERACTIVE BLADDER	23/12/2020	11/01/2021
UNITED STATES	CLASCOTERONE	WINLEVI	CASSIOPEA	ACNE	26/08/2020	04/01/2021

Price Changes: Europe & US

Country	Generic Name	Product Group	Company	Therapeutic Area	Avg. Price Change all SKU	First Pricing Date
SPAIN	FULVESTRANT	FASLODEX	ASTRAZENECA	ONCOLOGY	-25.00%	01/03/2006
UNITED STATES	CABOZANTINIB	CABOMETYX	EXELIXIS	ONCOLOGY	+7.50%	25/04/2016
UNITED STATES	INDOMETACIN	INDOCIN	EGALET	RHEUMATOLOGY	+9.90%	02/12/1985
UNITED STATES	PEGASPARGASE	ONCASPAR	SERVIER	ONCOLOGY	+9.35%	01/02/2014
UNITED STATES	ALITRETINOIN	PANRETIN	EISAI	ONCOLOGY	+9.91%	02/02/1999
UNITED STATES	ARSENIC TRIOXIDE	TRISENOX	TEVA	ONCOLOGY	+9.40%	11/10/2000
FRANCE	AFLIBERCEPT	ZALTRAP	SANOFI	ONCOLOGY	-10.00%	12/06/2013
GERMANY	BOSUTINIB	BOSULIF	PFIZER	ONCOLOGY	-10.44%	01/02/2014
GERMANY	LAMIV & TENO DISOP & DORAV	DELSTRIGO	MERCK	HIV	-2.09%	15/01/2019
FRANCE	ATEZOLIZUMAB	TECENTRIQ	ROCHE	ONCOLOGY	-4.76%	21/02/2019

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