PRICENTRIC ONE
BY EVERSANA™

INSIGHTS Newsletter

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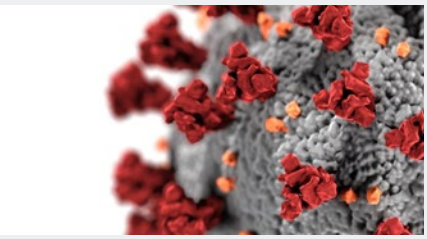
A Rundown of 2020 Trends in Pharma



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Navigating COVID-19: How Did the Pharma Industry Tackle the Pandemic in 2020?

PRICENTRIC BRIEF:

- In 2020, COVID-19 touched every aspect of our lives, wreaking havoc on numerous industries and forcing companies globally to re-evaluate their future
- The world has spent the last year tentatively watching pharma players for preventative and curative vaccines and treatments, all in a bid to the end the pandemic as quickly as possible
- From the get-go, manufacturers, regulatory agencies and governments put down the battle axes and pursued a collaborative approach

THE DETAILS

In 2020, COVID-19 touched every aspect of our lives, wreaking havoc on numerous industries and forcing companies globally to re-evaluate their future.

But one industry that was consistently in the spotlight was the pharmaceutical industry, hailed by the majority of the public as our light at the end of the tunnel. The world has spent the last year tentatively watching pharma players for preventative and curative vaccines and treatments, all in a bid to the end the pandemic as quickly as possible.

Coming Together

From the get-go, manufacturers, regulatory agencies and governments put down their battle axes and pursued a collaborative approach.

In the early days of the pandemic AbbVie took a pace-setting step by foregoing its patent rights for HIV med Kaletra (lopinavir/ritonavir) after government intervention in Israel. The compulsory license (CL), the tool that enabled the Israeli government to override the patent holders' rights and promote generic competition, was relatively unprecedented. Intellectual property (IP) rights are essential for the conventional running of the pharmaceutical industry but following example, CL is sure to now be something pharma companies will consider after the pandemic passes.

In a similarly communal move, leaders from the World Health Organization (WHO) and Unitaid were quick to welcome a proposal by Costa Rica which would involve companies voluntarily pooling their intellectual property for treatments, vaccines, and diagnostics for COVID-19.

Under the project governments or generic drugmakers would, on a voluntary basis, manufacture and sell products at much lower prices than currently available in the world market to all interested countries, a move that has previously been allowed for HIV/AIDS, tuberculosis, and hepatitis C treatments for only lower-income countries.

Transparency and Collaboration

While voluntary, such a move requires pharmaceutical companies to be accountable and transparent, a topic that COVID-19 has brought to light, even more so than usual.

As the pandemic progressed, more collaboration efforts came to light, such as the global COVAX scheme, which is currently being led by the Global Alliance for Vaccines and Immunization (GAVI), the Coalition for Epidemic Preparedness Innovations (CEPI), and WHO.

The pooled procurement mechanism for new COVID-19 vaccines has more than 172 countries under its belt, as well as the European Commission. The involved countries also pledged to support 90 lower-income countries by financing the vaccines from their own national budgets and through voluntary donations to GAVI's COVAX Advance Market Commitment (AMC).

The initiative was intended to help share the risks associated with vaccine development, investing in manufacturing upfront so vaccines can be deployed as soon as they're proven to be effective and safe. COVAX is also involved in pooling procurement and purchasing power to achieve sufficient volumes – up to two billion doses – of the vaccine to try and end the pandemic in 2021.

Expedited Frameworks

COVID-19 kickstarted a number of expedited clinical and regulatory processes, some of which could hold-fast even after the pandemic is over.

The Government of Russia has decided to extend its procedure for the accelerated approval of medicines for COVID-19 until January 1, 2022, according to Prime Minister Mikhail Mishustin.

Belgium's Federal Agency for Medicines and Health Products (FAMHP) also began processing clinical trials of drugs for the treatment or prevention of COVID-19 in four business days, instead of the usual timeline of two weeks to a month.

More recently, the South African Health Products Regulatory Authority (SAHPRA) noted that applications for COVID-19 medicines must be expedited due to the urgency of the pandemic, and if some applications do not fully align with ZA-CTD requirements, challenges may arise in the Agency's approach to assessment.

Re-localizing Manufacturing

There has been a lot of discussion about re-localizing medicine production to in order to help try and mitigate medicine shortages, particularly to Europe, which seeks to lessen its dependence on supplies coming from places like Asia.

Asia is the biggest supplier of medicines to the UK, with a handful produced in Europe and about 20% to 25% made in the UK, according to the British Generic Manufacturers' Association (BGMA).

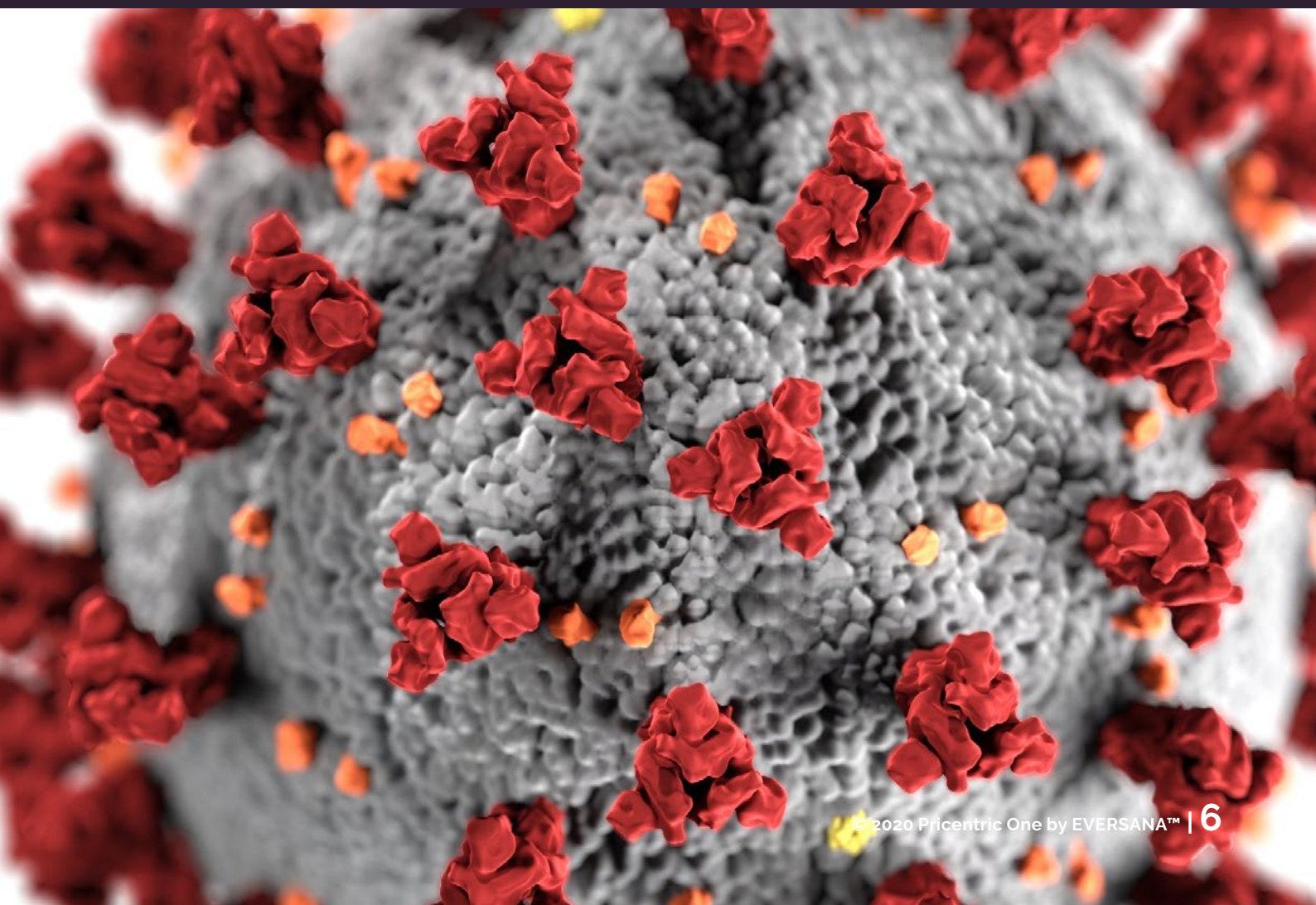
The pharmaceutical industry has taken on board issues that have arisen over the course of COVID-19 and is in the process of determining whether bringing more production capacity back to Europe will be beneficial to ensure the continual supply of medicines and medical devices in the future, especially in the context of future crisis.

Future Pandemic Preparedness

If anything can be taken as a silver lining from the struggle of the last year, the pandemic has spurred on the pharmaceutical industry to think about future crisis, with President of the European Commission, Ursula von der Leyen, announcing a set of proposals that aim to strengthen the European Union's health security framework, and to reinforce the crisis preparedness and response role of key EU agencies.

Speaking at her State of the Union address in November, von der Leyen noted: "Our aim is to protect the health of all European citizens. The coronavirus pandemic has highlighted the need for more coordination in the EU, more resilient health systems, and better preparation for future crises."

Pharma companies have also done some crisis-related introspection and determined that going forward, strengthening their supply chains will help mitigate any future crisis impact, as well as investing in digitalization and remote capabilities.



Germany's GSAV Law Takes Test Drive with Zolgensma

PRICENTRIC BRIEF:

- Germany's "Better Safety in Drug Supply" (GSAV) law empowers G-BA to utilize real world evidence for quality assurance monitoring of advanced therapy medicinal products (ATMPs) and orphan drugs, and Zolgensma by Novartis subsidiary AveXis was the subject of G-BA's first pilot assessment
- G-BA crafted a new procedure to collect post-launch data for Zolgensma divided into three steps: assessing the need for data collection and initiation of proceedings, consulting expert bodies, and making a decision on the requirement for data collection
- While Zolgensma's orphan drug evaluation was ultimately suspended due to surpassing a sales threshold, it still functioned as a useful pilot therapy that triggered the signing of success-based contracts and prompting the G-BA to assemble guidelines for post-launch data collection and treatment standards for ATMPs launched in the future

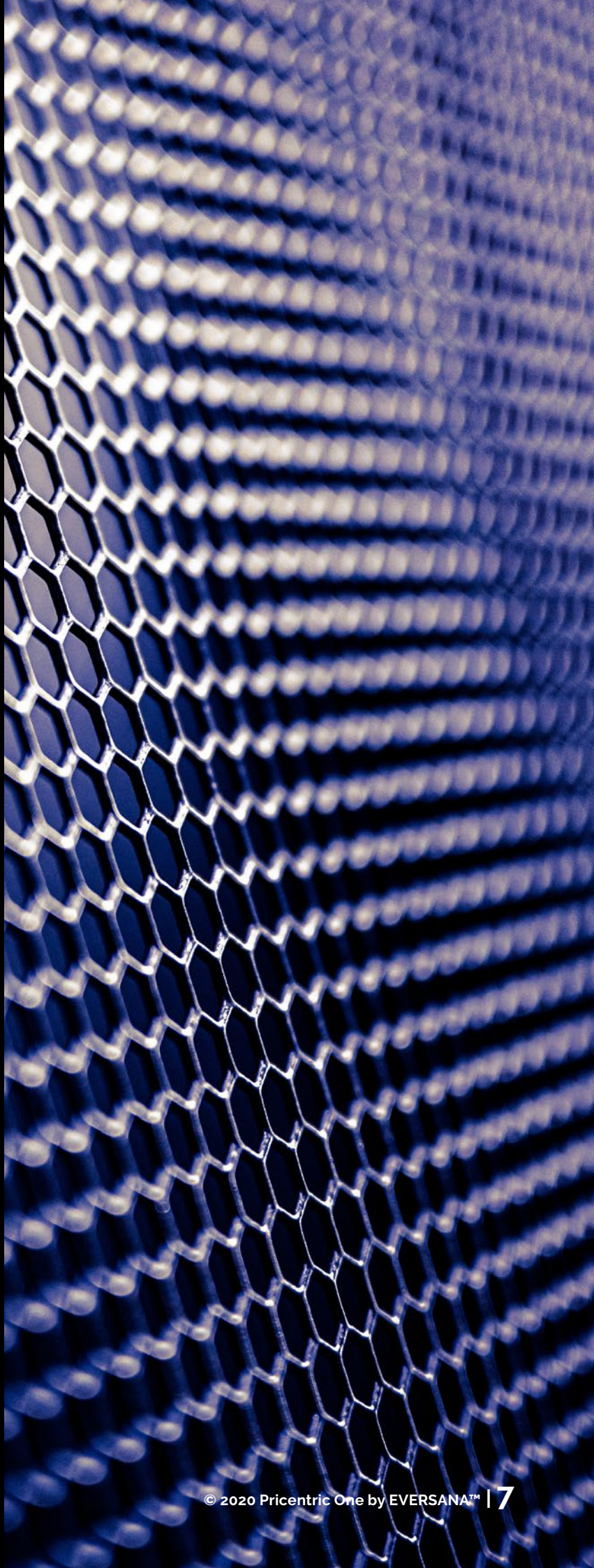
THE DETAILS

BERLIN, Germany — Passed by the Higher Chamber of Parliament and enacted in August 2019, Germany's "Better Safety in Drug Supply" (GSAV) law seeks to boost biosimilar usage, more strictly control pharmacy practices, digitalize the healthcare system with the enactment of e-prescriptions, and enhance the government's quality assurance monitoring of advanced therapy medicinal products (ATMPs) and orphan drugs.

Jens Spahn, Federal Health Minister, said, "The law aims to make the supply of medicines better and safer. Patients need to be sure that medicines help and do not harm them"

On the topic of monitoring new drugs, the law empowers G-BA to utilize real world evidence, though G-BA will define the specific requirements regarding the data collection thus differing from the international understanding of real world evidence.

The G-BA's original press release said, regarding the new requirements, "For some [orphan] drugs, complete clinical data for assessing the added benefit were not yet available at the time of approval. The aim of the application-related data collection is therefore to close existing gaps in knowledge and at the same time to make the relevant pharmaceuticals



available to patients in the statutory health insurance quickly, so that a better database can be created as early as possible for assessing the additional benefit."

Each year, the G-BA reassesses the benefit based on the newly available evidence, and price negotiations subsequently take place. Zolgensma was the subject of G-BA's first pilot assessment, which was published in July 2020.

Zolgensma as Trailblazer

Back in April 2020, German health insurance service company GWQ ServicePlus AG and Novartis subsidiary AveXis concluded a success-based reimbursement contract for Zolgensma (onasemnogene abeparvovec), a gene therapy used for the treatment of spinal muscular atrophy (SMA).

The payer referred to the drug as the most expensive drug in the world, and said the agreement protects them from the financial risk of therapy failure.

As explained by GWQ ServicePlus AG in a press release, "In contrast to previous contracts with a similar innovative reimbursement model, several patient-relevant outcome parameters are taken into account in this contract model, whereby AveXis assumes the risk of repaying up to 100% of the pharmaceutical costs in stages in the event of a contract."

The health insurance companies under GWQ ServicePlus AG and AveXis jointly bear the financial responsibility for the gene therapy and would like to adjust the costs of the therapy to the benefits in real everyday care.

Upon approval of Zolgensma, GWQ ServicePlus AG aims to ensure immediate access for patients. In Germany, around 80 SMA patients are born each year.

At the end of March, The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending conditional marketing authorization for Zolgensma.

CHMP's opinion pertains to Zolgensma as treatment of patients with 5q muscular atrophy (SMA) with bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type 1; or for patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to three copies of the SMN2 gene.

In March, the first infant in Germany with SMA was treated with Novartis' Zolgensma (onasemnogene abeparvovec) under the hardship program agreed to by the Paul Ehrlich Institute (PEI) in early February.

Under the scheme, Zolgensma is made available by AveXis, and the program for Germany was scheduled to end as soon as Novartis' gene therapy received approval in Europe.

Days later, the Association of Private Health Insurance (PKV) became the second payer in Germany to sign a supply contract with AveXis for Zolgensma, announced the association.

According to PKV, the contract between PKV and AveXis ensures those with private insurance are guaranteed immediate access to Zolgensma upon European approval.

Babies diagnosed with SMA will be treated with Zolgensma in highly specialized centers with experience in the treatment of pediatric neuromuscular diseases, and the contract includes a success-oriented reimbursement agreement.

Florian Reuther, PKV Association Director, said, "With the contract we have legal certainty and can guarantee the high quality of care for our insured."

Zolgensma Priced at € 1,945,000 in Germany

In June 2020, through value-based pricing, it was determined that the cost of Zolgensma should be € 1,945,000 in Germany, according to AveXis.

Upon receiving conditional approval in Europe, it was announced that Zolgensma would be launching in Germany "very shortly."

Andrea Hofmaier, General Manager, AveXis Germany, commented, "Germany is one of the first countries worldwide to use the gene therapy soon as a treatment option for SMA patients. …This new technology heralds a new era in SMA treatment and is innovative in many ways – including the type of reimbursement. We want to go through agreeing performance-based reimbursement models with financial responsibility carrying health insurance companies together."

While AveXis awaited a health technology assessment (HTA) to determine the drug's level of added benefit under AMNOG, the company searched for health care partner refunds that promote rapid patient access to the gene therapy.

G-BA Crafts New Procedure to Evaluate Zolgensma

In July 2020, The Federal Joint Committee (G-BA) outlined its process to collect post-launch data for Zolgensma.

G-BA is responsible for evaluating the added benefit of medicinal products with conditional approval. Sometimes, orphan drug products, which intend to treat rare diseases, have limited clinical data—or, in the case of Zolgensma, no meaningful data, according to G-BA—which impacts how effectively they can be assessed.

The G-BA decided to amend its rules of procedure to assess Zolgensma though the rules would first require approval by the Federal Ministry of Health.

In a press release, G-BA explained, "For Zolgensma, a recently approved gene therapy for spinal muscular atrophy, the G-BA determined for the first time the need for data to be used in conjunction with the application, as there is so far no meaningful data for assessing the long-term benefit or harm of the treatment and there is no comparative data on alternative therapies."

Its procedure was divided into three steps: assessing the need for data collection and initiation of proceedings, consulting expert bodies, and making a decision on the requirement for data collection.

For the first step, information from study reports was to be used to assess whether data collection is required to fill in possible evidence gaps, in professional exchange between the Federal Joint Committee (G-BA) and the Federal Institute for Drugs and Medical Devices (BfArM) and the Paul Ehrlich Institute (PEI).

This would also allow for comparing current and planned data collection, including what needs to be considered, by ancillary parties to cut down on duplication.

Next, G-BA would determine that data collection is necessary, which entails its sub-committee preparing a draft concept within six months. The Federal Institute for Health and Care Excellence (IQWiG) would be called upon by G-BA to prepare the draft concept. Included in the concept would be the duration and scope of data collection and the methodology of data collection, among other factors.

Via the next step, the draft concept for assessing Zolgensma would be reviewed by experts from BfArM, PIE, and other scientific and medical associations. The pharmaceutical company could also weigh in if need be.

Lastly, the G-BA would determine during a plenary session whether it would require data collection, and it would need to specify what must be observed. G-BA planned to review the process of data collection, at minimum, every 18 months. This would allow G-BA to decide if the process is sufficient to collect evidence.

G-BA Draws Up High-Quality Treatment Standards

In November 2020, the G-BA announced all specialist centers and hospitals that want to administer Zolgensma for SMA must comply with high-quality standards defined by the agency.

Institutions must show they have the proper infrastructure, organization, and nursing and specialized medical staff for neuromuscular disease, specifically SMA, to not only reduce the risk of complications, but to ensure data is effectively collected for the SMA patient registry.

G-BA's requirements are planned to take effect within two months of the announcement, pending no feedback from the Federal Ministry of Health (BMG). From then, treatment centers and hospitals will have six months to comply.

According to Josef Hecken, G-BA Chairperson and Pharmaceuticals Subcommittee Chair, little is known about the acute and long-term side effects and complications of treatment with Zolgensma. At the time the gene therapy was granted conditional approval in Europe, the data situation was "very weak," explained Hecken.

G-BA still planned on assessing the extent of the added benefit of Zolgensma and present findings on its therapeutic benefits and side effects. In February, Zolgensma was planned to undergo application-related data collection. The collection would focus primarily on the effect of Zolgensma in babies, toddlers, and infants, as its use beyond this age group is less frequent.

Through this, G-BA wants to collect data from the ongoing care of patients to better assess Zolgensma considering alternative treatment options, including Biogen's Spinraza (nusinersen) and patient-specific supportive treatment.

When it comes to treatment centers, G-BA is of the opinion that those who meet requirements for administration of Zolgensma and patient support need not re-submit individual applications for the gene therapy.

Orphan Drug Evaluation Suspended, Sales Crossed EUR 50 Million

In December, the G-BA suspended its orphan drug assessment procedure for Zolgensma since sales of the gene therapy have topped EUR 50 million.

The orphan drug assessment of Zolgensma was supposed to have wrapped in December but sales exceeded the stipulated threshold for orphan drugs in Germany, meaning the gene therapy will become subject to standard G-BA assessment.

Prof. Josef Hecken, Impartial Chair of G-BA and Chair of the Pharmaceuticals Subcommittee, commented, "This is now not possible, as the orphan drug privilege will no longer apply due to the very high sales in Germany since market entry in July 2020 and a more detailed assessment is necessary."

Hecken continued, "On the basis of the available studies - and not just on the basis of the approval documents - we will now examine what we currently know about the medical benefit and additional benefit compared to an appropriate comparator therapy and where there are still gaps. Data on long-term risks and the sustainability of the therapeutic effects will not be available in the upcoming regular benefit assessment either, however, the entrepreneur must present comparative data against the existing therapy alternatives. It is also about

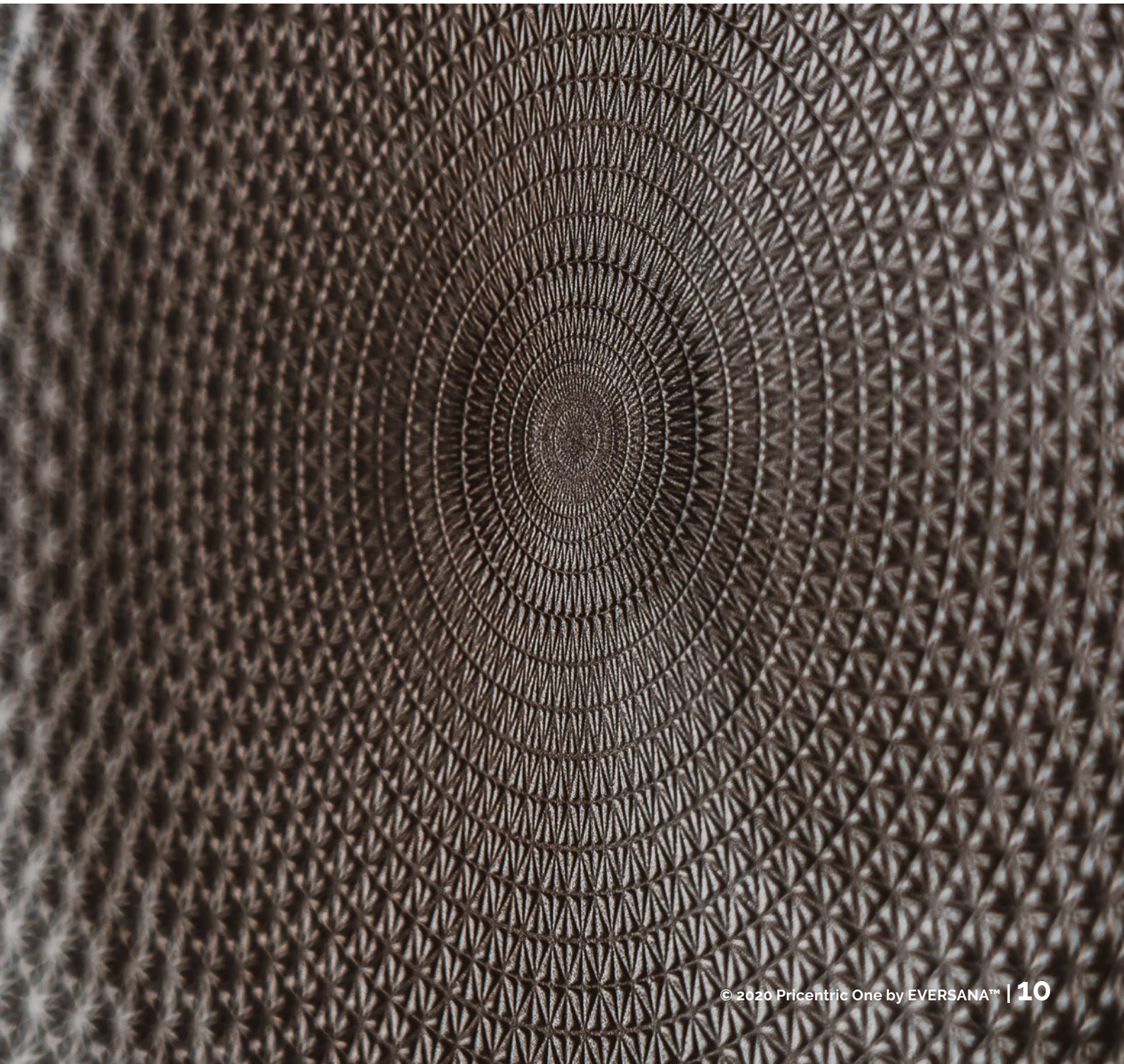
the question of whether, for example, certain age groups particularly benefit from therapy with Zolgensma. The one-armed approval studies alone will not be sufficient for this."

Regulation of Zolgensma, Going Forward

In the meantime, Zolgensma can continue to be prescribed and used within the framework of its approval and in compliance with quality assurance standards, said Hecken, and Germany will decide on the application-related data collection in February.

Moreover, Novartis/AveXis can still freely determine the reimbursement amount for Zolgensma until June 30, 2021, since the evaluation result of the G-BA - which forms the basis for these negotiations - will probably not be available until November 2021, the subsequently agreed price will apply retrospectively to July 1, 2021.

While Zolgensma's orphan drug evaluation was ultimately suspended, it still functioned as a useful pilot therapy that triggered the signing of success based contracts and prompting the G-BA to assemble guidelines for post-launch data collection and treatment standards for ATMPs launched in the future. As with any new policy, twists and turns occur, like Zolgensma's rise past the sales threshold for orphan drugs, but these are learning opportunities for refining the industry pipeline. Going forward, Germany's regulatory authorities will have an easier time evaluating orphan drugs with limited data and regulating and monitoring their use in clinical settings.



What Post-Brexit Measures Does the Pharma Industry Have in Place Going into 2021?

PRICENTRIC BRIEF:

- On January 23 this year, the United Kingdom's (UK) European Union (EU) withdrawal bill officially became law, and eight days later the UK began the 11-month process of becoming autonomous
- Following the implementation of Brexit, the Medicines and Healthcare products Regulatory Agency (MHRA) will officially be the UK's standalone medicines and medical devices regulator from 1 January 2021, and despite COVID-19 taking precedent for most of the year, vital Brexit talks, deals and developments continued to be a focus for Prime Minister Boris Johnson and the government
- The MHRA, DSHC, EFPIA and various other organizations have all spent the year preparing guidance and giving advice on the ever-approaching end of the transition period

THE DETAILS

LONDON, United Kingdom – On January 23 this year, the United Kingdom's (UK) European Union (EU) withdrawal bill officially became law, and eight days later the UK began the 11-month process of becoming autonomous.

Following the implementation of Brexit, the Medicines and Healthcare products Regulatory Agency (MHRA) will officially be the UK's standalone medicines and medical devices regulator from 1 January 2021, and despite COVID-19 taking precedent for most of the year, vital Brexit talks, deals and developments continued to be a focus for Prime Minister Boris Johnson and the government.

For both the UK and Northern Ireland, Brexit could cause disruptions to medicine supplies and regulatory issues, so what has been done since January 2020 to mitigate any potential disruptions?

Medicines and Medical Devices Bill

In February the Medicines and Medical Devices Bill was launched, with the aim to make licensing and regulation of new therapies more efficient and put into effect new regulations on medical devices, thus supporting patient safety and keeping the UK at the edge of health technology innovation.

The bill is meant to mitigate risk if drugmakers choose to seek EU approval for drugs first, thereby forcing UK patients to wait longer for treatment. Additionally, the bill enables hospitals to utilize patient tissue and DNA samples in order to customize treatments or develop drugs with a shelf-life of minutes, which would otherwise not be available. The measure would especially benefit cancer and brain tumor treatments.

COVID-19 Stockpiling

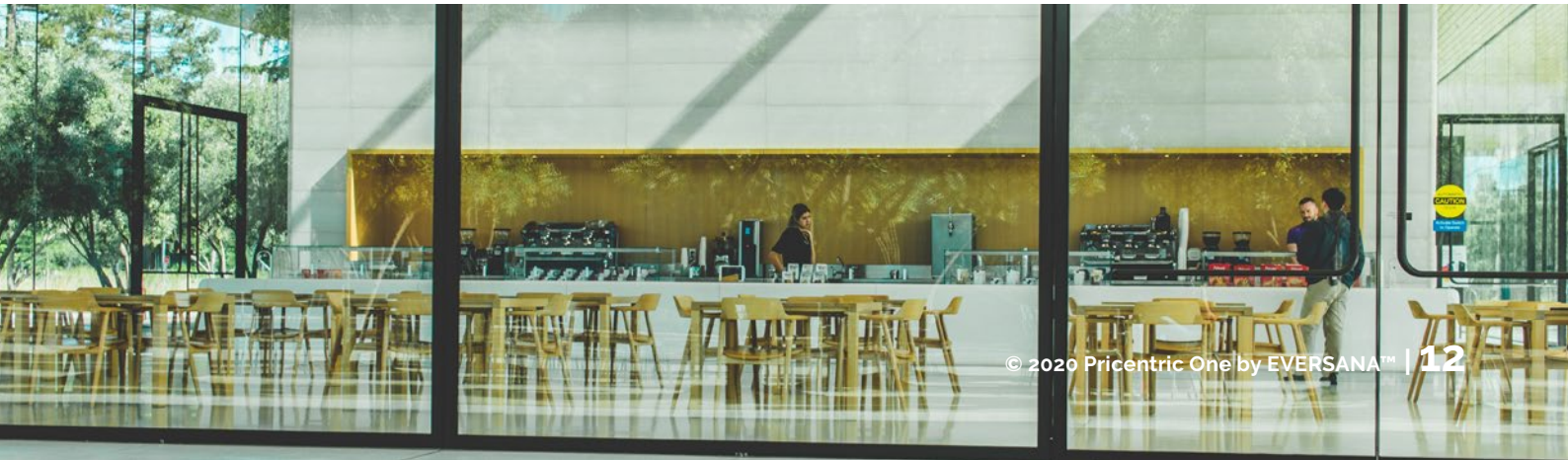
In June, it was revealed that stockpiles of certain medicines had been "used up entirely" as the COVID-19 pandemic took hold of the globe. At the time, companies expressed fear that stockpiles could not feasibly be built back up again in time, if the UK should fail to strike a post-Brexit trade deal with the European Union, adding that disruption to global supply chains would seriously impact the NHS.

The prospect of a no-deal Brexit continued to add to experts' concerns, as it could cause serious congestion at the ports of Dover and Calais, which is the route that 90% of imported drugs and medicines from the EU take to get to the UK.

Industry Feedback

As tensions rose, the European Federation of Pharmaceutical Industries and Associations EFPIA) wrote a letter to the Honorable Presidents and Commissioner, Honorable Chief negotiator, highlighting the need to prioritize patients' access to medicines in the EU-UK negotiations following the outcome of a high-level meeting of June 15, 2020, in which the board discussed creating the most conducive conditions for concluding and ratifying a deal before the end of 2020.

Also in June, Dr Louise Gill, Head of Policy at GlaxoSmithKline, told the Lords EU Goods Sub-Committee that should a no-deal Brexit occur, pharmaceutical exports to the EU would drop by more than a fifth (22.5%). The news only added to the government's ever-growing pressure from the pharmaceutical industry, as Boris Johnson continued to insist that he would not accept the EU's offer of a transition period extension beyond December 31, despite trade talks making slow progress.



DHSC, MHRA Publish Official Game Plans

Come August, the Department of Health and Social Care (DHSC) had officially written an open letter to drug suppliers, detailing concerns over the continuity of the supply of medicines and medical products to the UK.

In the letter, DHSC noted that during the remainder of the transition period, mitigating potential disruption to the following should be a point of focus:

- Medicines
- Medical devices and clinical consumables
- Clinical trials supplies
- Products of human origin (blood and transplant items)
- Vaccines and countermeasures
- Non-clinical goods and services (NCGS) in support of health and social care providers

The group suggested re-routing away from the short straits such as the aforementioned Calais/Dunkirk/Coquelles and Dover/Folkestone passages, as a large percentage of medical supplies come from the EU or have a supply touchpoint there.

Edging ever-closer to 2021 and the end of the transition period, the MHRA also published its comprehensive guidance for the pharmaceutical industry on everything from clinical trial practice, to pharmacovigilance and licensing in September.

On the release, the MHRA said that the final transition from the EU will allow the UK to "offer fully independent regulatory decisions for both devices and pharmaceuticals, both nationally and in joint work with other international regulators." The MHRA will officially be able to issue its own conditional marketing authorizations from 2021, working on a similar basis to that of existing European systems.

Northern Ireland Concerns

Despite the release of the official guidance, health officials still had a "primary concern" that the Brexit transition period would endanger the flow of medical and health care supplies into Northern Ireland; Around 98% of medicines used in Northern Ireland are transported from Great Britain through local ports and the majority of those are distributed through the UK wholesaler network.

Fortunately, by December an agreement was reached on how to handle borders and trade going forward, following talks led by Cabinet Office Minister Michael Gove and Maros Sefcovic from the European Commission, in which they came to an "agreement in principle," although the details have not been disclosed.

2021 and Beyond

Whatever conclusion the UK's Conservative government comes to, as of January next year the UK will cease to participate in EU regulations on medicines, whether or not they manage to reach a deal.

The Institute for International and Development Economics (IIDE) published a study on the economic implications for Europe for three different types of trading relationships between the European Union (EU) and the United Kingdom, exploring a no-deal scenario (trading under WTO rules), a simple free-trade agreement (FTA) limited to covering tariffs for all sectors, and an FTA that includes mutual recognition agreement (MRA) on GMP inspections and batch testing in addition to tariff liberalization.

Compared to a No Deal scenario, under an FTA with MRA, EU nominal GDP would be 1.3 billion euros higher annually, with an export drop of only 0.9%, a difference of 1.2 billion euros annually in favor of an FTA with MRA. As such, EFPIA, among other bodies, has suggested that a mutual recognition agreement is probably the most beneficial type of relationship for Europe going forward.

With just a matter of days to go, all eyes are on Boris Johnson to lead the country to the smoothest resolution possible.

Europe Set to Tackle its New Pharmaceutical Strategy from 2021

PRICENTRIC BRIEF:

- In November 2020 the European Commission (EC) adopted a new Pharmaceutical Strategy for Europe, covering everything from access and affordability to competition support and frameworks for innovation
- The plan is primarily a crisis response outline, building on lessons learned from COVID-19, in order to better prepare for future potential pandemics and other crisis
- Another primary feature of the plan is to support the competitiveness and innovative capacity of Europe's pharma industry, as well as revising the EU's pharma legislation in order to simplify and ultimately streamline regulatory frameworks

THE DETAILS

BELGIUM, Brussels – In November 2020 the European Commission (EC) adopted a new Pharmaceutical Strategy for Europe, covering everything from access and affordability to competition support and frameworks for innovation.

The project will be proposed by the end of 2021 according to the EC, and will be based on four specific pillars, which include legislative and non-legislative action:

- Ensuring access to affordable medicines for patients, and addressing unmet medical needs (e.g. in the areas of antimicrobial resistance, rare diseases);
- Supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines;
- Enhancing crisis preparedness and response mechanisms, diversified and secure supply chains, address medicines shortages;
- Ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

The plan is primarily a crisis response outline, building on lessons learned from COVID-19, in order to better prepare for future potential pandemics and other crisis.

The agenda will be implemented over the coming years, and tackle issues such as cooperation between national authorities on pricing, payment and procurement policies in order to help improve affordability and cost-effectiveness of drugs.

Another primary feature of the plan is to support the competitiveness and innovative capacity of Europe's pharma industry, as well as revising the EU's pharma legislation in order to simplify and ultimately streamline regulatory frameworks.

Before she officially announced the outline of the plan, President of the European Commission, Ursula von der Leyen explained: "We are changing the way we address cross-border health threats. Today, we start building a European Health Union, to protect citizens with high quality care in a crisis and equip the Union and its Member States to prevent and manage health emergencies that affect the whole of Europe."

Feedback

The European Federation of Pharmaceutical Industries and Associations (EFPIA) "welcomed" the Strategy, but simultaneously expressed that it believes "the approach to addressing access and affordability outlined in the Strategy is the wrong one."

A number of the detailed points in the plan are in a similar vain to EFPIA's own 'Regulatory Road to Innovation', which focuses on strengthening regulatory assessment, working on use of RWE in decision making and streamlining pathways for regulation of devices with drugs.

EFPIA Director General, Nathalie Moll specifically noted that "In tackling AMR, the Strategy recognizes

the importance of incentives in driving research into unmet medical need. However, at the same time, the Strategy suggests destabilising and weakening incentives designed to support innovation in multiple areas including for medicines for rare diseases and children, as a way of addressing issues of access and affordability of medicines."

EVERSANA Insight

On the release of the plan, EVERSANA's Europe and Asia-Pacific Vice-President, Mike Ryan, reminded that "patient access and health data collection has been hindered by increasing drug development costs and, subsequently, pricing, as well as inconsistent drug availability across the EU. The onset of COVID-19 further emphasized the need to improve patient access, drug affordability, competitive pricing, and overall crisis preparedness and response in the EU healthcare system.

"In particular, the EU will encourage greater incorporation of health technology assessment (HTA) requirements in the design of clinical trials and subsequent closer collaboration between HTA authorities. The EU is advocating greater consistency in the data requirements for HTA approvals in all member states.

"This urgent push for affordable pricing will, the EU believes, contribute to increased competition among pharmaceutical companies in the EU healthcare system. As competition escalates, especially between generic and biosimilar drugs, pharma companies will need to meet heightened standards in HTAs and efficacy as well as supply chain demands."

Putting the Strategy into Action

Consultations with member states at the political level began in December 2020, and implementation of the various aspects is expected to occur as imminently as possible.

Going forward, the Commission has outlined a number of priority "flagship" actions, including a revision of the basic pharmaceutical legislation with a proposed target date of 2022.

The strategy outlines a proposal for an EU Health Emergency Response Authority, dubbed HERA, which has been planned for the second half of 2021.

The long-term project also wants to initiate a structured dialogue with and between all actors in the pharmaceutical manufacturing and public

authorities to "identify vulnerabilities in the global supply chain of critical medicines and shape policy options to strengthen the continuity and security of supply in the EU."

Some aspects of the strategy have been met with almost unanimous approval, such as pan-European HTA, accelerated marketing authorization, parallel scientific advice on trial design, optimized SPCs, European Health Data Space, and support for innovative trial designs, according to Neil Grubert, founder of Future of Pharmaceutical Market Access group.

Grubert noted, however, when speaking at the 3rd Annual Pharma Pricing, Reimbursement & Market Access 2020, that other aspects of the plan are somewhat uncertain in terms of impact on industry.

These parts of the framework include research on the root cause of market access delays, improving the competitive functioning of markets, developing framework for repurposing off-patent medicines, and the use of digital technology to tailor incentives for innovation.

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

Accurate

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

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

China's Centralized Procurement: Full Steam Ahead

Scores of medicines have become available in public hospitals across China after three rounds of procurement were successfully administered this and last year.

Altogether, the China's central government facilitated the national procurement of over one hundred medicines for city hospitals and other public health institutions, with many prices slashed by 52-54%, on average, saving the medical insurance fund tens of billions of yuan.

With a draft list already sketched out for a fourth round, the program is running full steam ahead, with a wake of potential future price reductions for medicines yet to undergo procurement.

Trial & First Round

In November 2018, the "National Drug Centralized Procurement Organization Pilot Scheme" launched in China. The final policy document indicated that the scheme would cover 11 cities— termed "4+7," since the plans cover 4 municipalities and 7 provincial cities. A list of 31 drugs targeted for procurement under the scheme was published. Ultimately, the pilot program, though only focused on 11 cities, saw the prices of these drugs cut down by an average of 52%.

China subsequently expanded its nationalized procurement trial in September 2019, from the 11 trial cities to 25 cities to further reduce costs for more stakeholders. A total of 77 pharmaceutical companies participated in the September round of bidding, of which 45 were accepted. The average price of winning bids was 25% lower than prices set during the previous year's pilot program, according to a statement issued by the office overseeing the test.

During the expanded trial, foreign drugmakers were undercut by domestic drugmakers during tendering for 25 medicines ranging from cholesterol treatments to chemotherapy.

Second Round

The Administration went ahead with a second round of centralized drug purchases at the start of 2020. The Shanghai Drug Purchase Network, the National Health Security Administration's (NHSA) executive for Round 2

of the National Level Centralized Drug Purchase Program, announced that Round 2 included the purchase of 33 drugs regarding 50 specifications.

The products were mostly for diabetes, hypertension, oncology, and rare diseases, with a total of 122 pharmaceutical companies partook in the bidding.

According to Chinese media, the average price reduction by prevailing suppliers in Round 2 was between 60% and 80%, with the highest single price reduction at 93% from Hunan Jiudian Pharma for levocetirizine oral regular release dosage forms.

The total purchase value for Round 2 was anticipated to exceed CNY 8.7 billion. For 15 of the 33 drug products under Round 2, the purchase value was expected to exceed CNY 100 million.

The purchase value of Acarbose was the highest at CNY 2.9 billion.

Domestic manufacturers that participated in the bidding and won big include Qilu Pharma, Kelun Pharma, Yangzijang Pharma, Shijiazhuang Pharma, and Hengrui Medicines, and 26 foreign drugmakers participated, including Bayer, GSK, Pfizer, Sanofi, and Servier.

Third Round

In mid-August, the third round of national volume-based procurement (VBP) was wrapped, with an average price reduction of 53%, according to the National Healthcare Security Administration (NHSA).
The third round of procurement was China's biggest yet, with 56 drugs by generic name with 86 product specifications on the table and more cities are joining in. (To see which drugs were included in the 3rd round of VBP, click here.)

During the tender, 189 companies partook in the bidding to supply public medical institutions, including hospitals, with their medicines. All in all, 125 companies won bids involving 191 products, representing 55 of the initial lot of 56 drugs.

For the list of prevailing products from the latest tender (in Chinese), please click here. Generally, if a single company won the bidding, it could provide half of the total procurement volume in the first year, while with four winners, 70%-80% of the volume could be shared. Quoting higher prices, foreign companies often struck out during tendering, as, in some cases, domestic manufacturers offered price cuts of 90% to some products. When foreign drugmakers did secure a contract, they had to offer significant price cuts to compete in the aggressive tender.

According to preliminary results, contracts in China for AstraZeneca's (AZ) Brilinta (ticagrelor) and Eliquis (apixaban), jointly developed by Pfizer and Bristol-Myers Squibb (BMS), were won by Chinese companies.

Fortunately, brand name drugs fared well overall, particularly in the market not covered by the national procurement scheme, due to their higher profile among doctors compared to their generic counterparts.

Chinese media noted that the bidding for generic drugs has begun to concentrate around a few major players, such as Shanghai Pharmaceuticals Holding, who won bids for six products alone, most likely due to China's pressure on domestic drugmakers to focus on and produce high- quality generics.

Fourth Round

As 2020 ends, China has begun prepping for its fourth round of national volume-based procurement (VBP), its tentative list for this round consisting of 44 products with 90 specifications.

Most drugs on the list are chemical drugs, either available in oral regular-release forms or as injectables, and are intended for more than one specification. Notable anti-cancer medicine Bayer's Nexavar (sorafenib) for liver, kidney, and thyroid tumors made the list but could face generic competition, as China-based Jiangxi Shanxiang and Fosun's Chongqing Yaoyou both have sorafenib generics approved in China, according to Sina news.

However, biologic and biosimilar medicines, as well as traditional Chinese medicines were left out in the unofficial fourth national procurement list, despite rumors suggesting otherwise, reported Chinese media.

The unofficial list for the fourth round of national volume-based procurement is on the following page.

Unofficial List – China's 4th Round VBP

Esomeprazole (oral regular release)

Amisulpride (oral regular release)

Ambroxol (injection)

Olopatadine hydrochloride (eye drops)

Pyrazinamide (oral regular release)

Propofol (medium and long chain fat emulsion injection)

Ibuprofen (oral regular release)

Ibuprofen (injection)

Duloxetine (oral dosage form)

Doxofylline (injection)

Empagliflozin (oral regular release)

Tenofovir emtricitabine (oral regular release)

Voriconazole (oral regular release)

Gliclazide (sustained, controlled-release)

Gabapentin (oral regular release)

Canagliflozin (oral regular release)

Quetiapine (sustained, controlled-release)

Loxoprofen (oral regular release)

Loratadine (oral regular release)

Mosapride (oral regular release)

Nateglinide (oral dosage)

Norfloxacin (oral regular release)

Parecoxib (injection)

Pantoprazole (oral regular release)

Pantoprazole (injection)

Perindopril (oral regular release)

Bortezomib (injection)

Pramipexole (sustained, controlled-release)

Pramipexole (oral release)

Pregabalin (oral regular release)

Dobesilic acid (oral regular release)

Repaglinide (oral regular release)

Salbutamol sulfate (solution for inhalation)

Sorafenib (oral regular release)

Terbinafine (oral regular release)

Ticagrelor (oral regular release)

Telmisartan (oral regular release)

Temozolomide (oral regular release)

Cefprozil (oral regular release)

Hyaluronic (acid eye drops)

Valsartan and amlodipine (oral regular release)

Valsartan hydrochlorothiazide (oral regular release)

Bivalirudin (injection)

Levofloxacin (oral regular release)

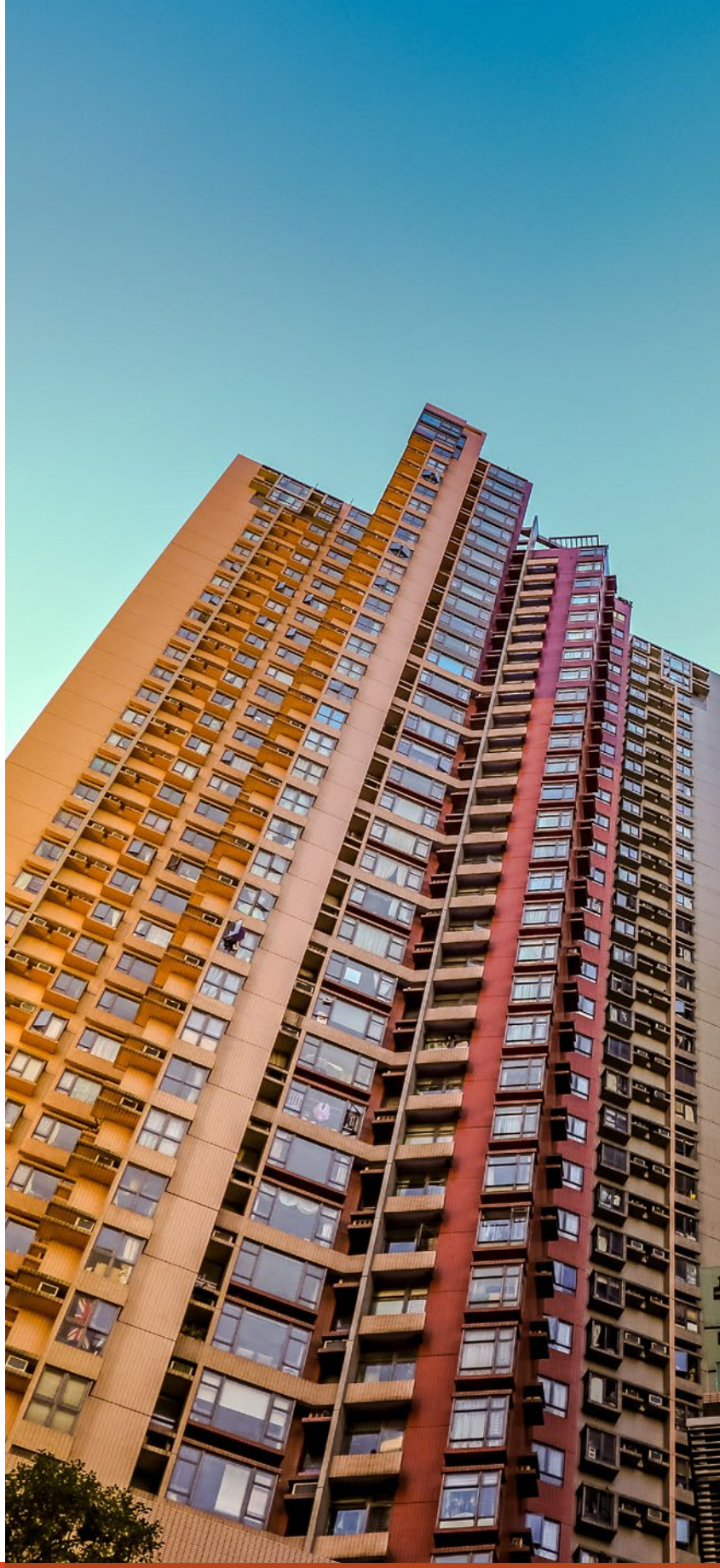
A deadline of December 21 has been noted for China to finalize the necessary volumes of these products for participating cities and their medical institutions.

Future Trajectory

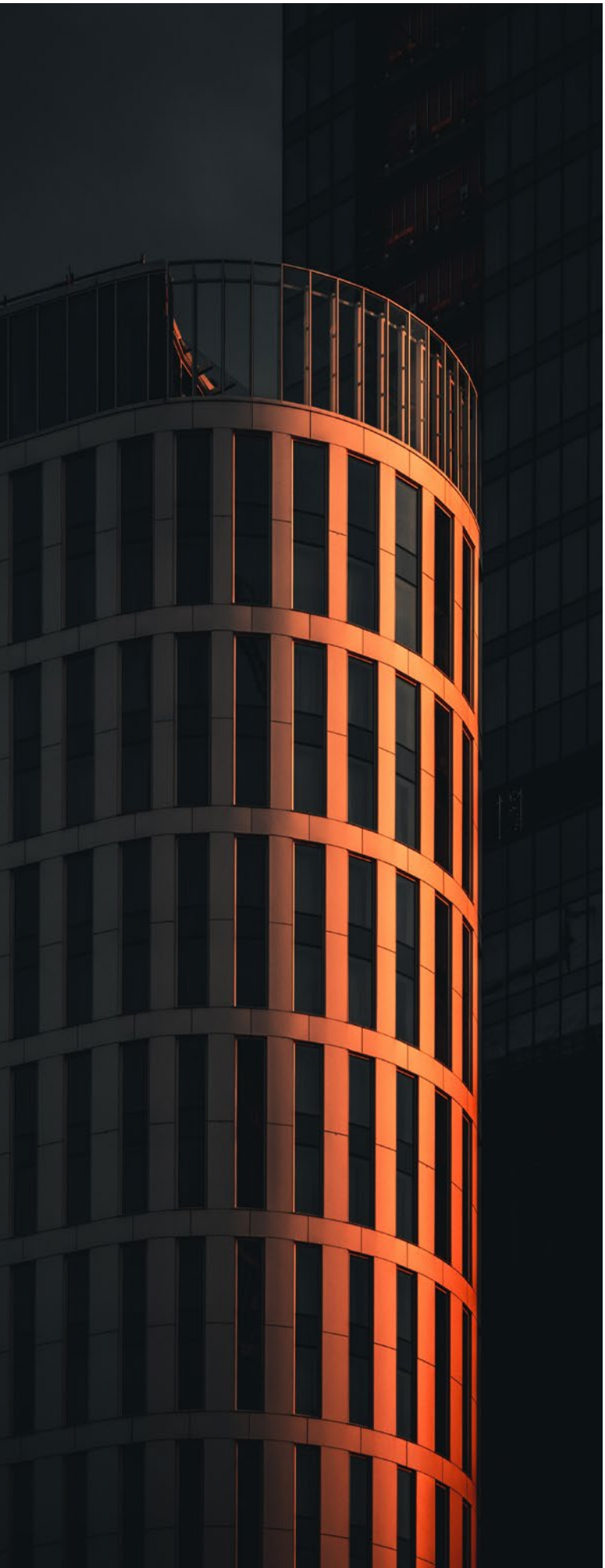
Han Zheng, Member of the Standing Committee of the Political Bureau of the CPC Central Committee and Vice Premier of the State Council, previously said it is necessary to accelerate the expansion of the scope of centralized procurement and strengthen the quality supervision of the selected products throughout the life cycle, including implementing 'zero tolerance' for quality problems.

Purchasing officials from China's provinces laid out the trajectory for centralized procurement over the next couple of years. Going forward, the national volume-based procurement (VBP) will expand nationwide to cover the top 250 drugs by national purchase value in 2021 and then 80% of leading drugs by national purchase value – a list that includes 500 products – in 2022. The market size of these 500 drugs is estimated to reach a staggering total of CNY 1.1 trillion.

In tandem with China's expanding basic medical insurance (BMI), the national centralized procurement of medicines reflects China's growing interest in finding areas to rein in costs in the health sector. As seen through China's first three rounds of VBP, the government is heavily focused on securing large volumes of widely used medicines at significantly discounted prices. The trend is set to continue into 2022, with more domestic drugmakers encouraged to produce good quality generics to submit for the tender. Further discounts as a result of competitive bidding can be expected going forward.



A Look Back at IRP in 2020



The United States and Canada made headlines this year for changes both countries will be implementing regarding the way they price medicines, particularly those with higher costs. Although stalled twice, come the new year Canada's Patented Medicines Price Review Board's (PMRPB) rule will take effect. 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. In the U.S., President Donald Trump signed his "Most-Favored Nations (MFN)" rule, which provides the U.S. with a basket of reference countries for the first time, a significant policy change for the States.

However, other updates were enacted around the world, this year.

IRP Updates That Took Effect This Year in Europe

Some changes in Europe were small, in response to Brexit. For example, Belgium is no longer referencing the United Kingdom since it formerly withdrew from the European Union.

In Latvia, medicine prices must be the average of the three lowest ex-factory prices among Latvia's reference basket countries. As of April 1, 2020, in order for medicines to be included in the reimbursement system, their price must not be higher than the second lowest manufacturer's sales price or wholesale price in the Czech Republic, Denmark, Romania, Slovakia, and Hungary, and must not exceed the manufacturer's selling price or wholesale price in Estonia and Lithuania.

Drugmakers will have to submit to the National Health Service (NSS) information on current prices in these countries by February 1 of each year. If the price does not meet the requirements, the applicant will have to reduce it.

As with Canada, the Netherlands experienced a delay in the implementation of its updated IRP schemes due to the impact of COVID-19 on the drug supply. The Netherlands held off on implementing its new international reference pricing IRP rule from April 1, 2020, to October 1, 2020. Via the Medicines Pricing

Act (WGP), maximum prices are applied in the Netherlands based on the average price for comparable medicines in 4 reference countries: Germany, Belgium, France, UK. However, the Netherlands will be swapping out Germany with Norway because in Norway, medicine prices are 20% less than they are in Germany.

Ukraine also trudged forward with implementing reference pricing for the first time. Ukraine is relying on the average price among Poland, Slovakia, Hungary, Czech Republic and Latvia to conduct IRP both at launch and every year.

Russia

In 2019, Russian President Vladimir Putin signed a bill establishing a new methodology for regulating the prices of medicines in the Vital and Essential Drugs List (VED). Although this bill mandates reporting of price changes and re-registration, IRP has been in effect in Russia since 2010 and has been used for drugs in the VED that are produced outside Russia.

According to the rule, the marginal costs of original, patented drugs, as well as one of their respective generics on the Russian market were to be re-registered with the Ministry of Health.

Russia's reference basket for this is comprised of Hungary, Greece, Belgium, Spain, Netherlands, Poland, Romania, Slovakia, Turkey, France, Czech Republic and Country of origin. In this case, the price of a drug will be determined as the lowest price in one of the 11 reference countries (in particular Belgium, France, or Romania) or in the country of origin. After determining the minimum price for the drug, the Ministry of Health will decide on the cost of each of its generics, and the Federal Antimonopoly Service (FAS) will be allowed to demand a new price reduction from pharmaceutical companies if the cost of the drug falls in any of the reference countries.

The new pricing procedure will not affect drugs worth less than 100 rubles, vaccines, narcotic, and psychotropic drugs.

Middle East and Central Asia

Lebanon's new pricing policy was published January 2020. Price revision will now take place every four years as opposed to every three years, as was the case before the new rule was implemented. Price submissions must be made at the end of Q4 of the fourth year.

For foreign manufacturers' branded products, the minimum price is applied, whereas for local manufacturers of licensed branded products, generics and branded products, Lebanon will use a mix of reference pricing & IRP; however, in theory, it's free pricing. IRP is used as a benchmark (the price cannot exceed the IRP price), and for local generics, the price cannot exceed that of the branded original. As such, branded originals are privileged. In the case of orphan and innovative drugs, if the price changes by more than 10% in any of the reference countries the manufacturer

must submit a new price declaration form and announce the new price.

Neighboring Jordan will conduct IRP at launch, using the median price found among its reference basket. For re-referencing, the minimum price will be used. Jordan's basket is expected to include France, Spain, Italy, Belgium, Greece, Australia, Cyprus, Hungary, Ireland, Portugal, Czech Republic, Croatia, Lebanon, Georgia, Tunisia, Azerbaijan, and Slovenia.

In July, Uzbekistan began phasing in a reference pricing system to combat unjustified overpricing of medicines, but according to Sardor Kariev, Director of the Agency for the Development of the Pharmaceutical Industry, "We are not aimed at forcing enterprises to lower the price of drugs or sell them at cost...we just want prices to be predictable, so we can be oriented."

Uzbekistan formulated a reference basket consisting of Hungary, Russia, Ukraine, Poland, Tajikistan, Slovenia, Kazakhstan, Bulgaria, Belarus, and Kyrgyzstan. Its IRP scheme applies to generic drugs of domestic and foreign production, not original medicines of domestic and foreign production, and the manufacturer must register the medicine's price for wholesale and retail, noting the trade name, dosage form, dosage, concentration, volume and packaging.

In tandem with establishing a reference basket, the Agency for the Development of the Pharmaceutical Industry has been developing an online platform on which each manufacturer working in the market of Uzbekistan will have to indicate the selling prices of their medicines in 10 reference countries.

Countries to Watch in 2021

Despite setbacks and re-focusing of efforts caused by the coronavirus pandemic, countries that have been amid making changes to their IRP schemes are still intending to finalize their rules.

Colombia will be soon taking the average price among the following reference countries to determine the price of new medicines: Argentina, Australia, Brazil, Canada, and Chile.

In addition, Morocco is expected to update its IRP rules, following an assessment of the scheme since its implementation in 2013. Of note, the World Health Organization (WHO) has offered ongoing support to Morocco as it fleshes out its update.

In 2019, Malaysia announced its plan to utilize IRP to benchmark medicines prices in Malaysia against cheaper drug prices in certain countries so that Malaysia's prices don't exceed the benchmark. The ceiling price will be based on the average of the three lowest prices, which will be imposed at the wholesale stage and retail level (in clinics, pharmacies, and hospitals).

Trump's "Most-Favored Nations" Rule: 2020 Was the Year of Reference Pricing in the United States

Among President Donald Trump's Executive Orders issued this year, the "Most-Favored Nations (MFN)" rule is undoubtedly the most striking policy change for the United States, introducing a reference price system for 50 Medicare Part B drugs that would price them in accordance with the lowest price among the MFN basket. The measure will significantly impact relevant prescription drug prices going forward. A pilot, its concretization is contingent on the outcomes of litigation and whether President-Elect Joseph R. Biden, who has thrown his weight behind leveraging the negotiating power of Medicare when determining drug prices, opts to keep it

THE DETAILS

WASHINGTON, D.C., The United States – In July, United States President Donald Trump announced four Executive Orders (EOs) on prescription drug pricing directing Secretary of Health and Human Services (HHS) Alex Azar to (1) pass on savings for insulins and epinephrine through the 340B program to patients, (2) end kickbacks, (3) allow the importation of certain prescription drugs, as well as re-importation of insulin, and (4) make sure Medicare beneficiaries and seniors pay no more for their medicines than any economically comparable OECD country.

At the time, Trump said, "The four orders that I'm signing today will completely restructure the prescription drug market, in terms of pricing and everything else, to make these medications affordable and accessible for all Americans."

The EOs aimed to pass on more discounts and savings to Medicare beneficiaries and not pharmacy benefits managers (PBMs) and allow the importation of re-importation of certain prescription drugs from abroad, specifically Canada.

According to Trump, PBMs have been "ripping off" Medicare beneficiaries, and from now on, these discounts will be passed on directly to patients at the pharmacy counter. "This will save patients up to 30 percent," said Trump. "It could be 40 percent, could be 50 percent, could be much higher than that."

However, Trump's import plan has since faced a major setback from the United States' northern neighbor, when Canada's Minister of Health Patty Hajdu announced, "Certain drugs intended for the Canadian market are prohibited from being distributed for consumption outside of Canada if that sale would cause or worsen a drug shortage."

Trump's MFN Rule Radical Policy Change for US

While impactful, these EOs are nowhere near as radical a policy change in terms of global and U.S. impact as Trump's "Most Favored Nation (MFN)" rule, the details for which were revealed at the end of November after it was signed in September. MFN stipulates that the U.S. will pay the lowest price among other developed nations, signaling the advent of reference pricing in the U.S. market.

According to the EO itself, "The MFN Model will focus on a select cohort of separately payable Medicare Part B drugs. This cohort will initially include 50 single source drugs and biologicals (including biosimilar biological products) that encompass a high percentage of Medicare Part B drug spending."

The price would match the lowest price paid among other wealthy nations that are part of the Organization for Economic Co-operation and Development (OECD). This list of countries

includes 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 for those drugs.

With the signing of this EO, HHS' Azar was directed to immediately take the steps to implement this plan to test a payment model pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price.

In addition, HHS Secretary Azar was directed to implement a payment model pursuant to which Medicare would pay, for Part D prescription drugs or biological products where insufficient competition exists and seniors are faced with prices above those in OECD member countries that have a comparable per-capita gross domestic product to the United States, after adjusting for volume and differences in national gross domestic product, no more than the most-favored-nation price, to the extent feasible.

As noted by Trump, both models were test whether paying more than the most-favored-nation price would mitigate poor clinical outcomes and increased expenditures associated with high drug costs for patients who require pharmaceutical treatment.

MFN Will Significantly Impact Drug Prices

MFN has received backlash from stakeholders across the board, including legal action, the most worrying points of concern being monumental price changes for drugs and the future of access to innovation in the U.S. The rule will lead to reductions in reimbursement (and hence price) for 50 drugs in the pilot program for Medicare Part B, which are physician administered drugs, typically infused drugs, as they are administered in a physician setting.

Take Roche's Avastin (bevacizumab), for example, which is currently reimbursed at approximately $139,000 in the U.S., whereas in Australia – one of Trump's MFN countries – has a current list price of a much more modest ~$39,000.

The rule allows a GDP adjustment. In the case of Australia, using the PPP approach outlined in the proposed rule, the adjustment would increase the $39,000 price slightly to allow for the different level of income.

OECD Countries	**CIA GDP Per Capita, Based on Purchasing Power Parity (2017)**	**GDP Adjuster for Performance Year 1, Quarter 1**
The following countries have a GDP per capita of at least 60 percent of U.S. GDP per capita:		
Australia	**$50,400**	**0.843**

EVERSANA Analysts review the four-year price erosion of one of the targeted products, the Roche monoclonal antibody based on the potential implementation of the clause, determining that in the first year, the U.S. Annual cost of therapy would be reimbursed at 75% of the current reimbursed price, and 25% of MFN country - in this case, Australia – price, after GDP adjustment, which would be ~ $46,250.

In the second year of the clause, the U.S. Annual cost of therapy would be reimbursed at 50% of current reimbursed price and 50% of MFN Price and so on and so forth until in the fourth year and beyond. The U.S. Annual cost of therapy is now reimbursed at 100% of the Australian MFN Price.

Following the erosion process, the MFN price of $46,250 would effectively become the new U.S. reimbursed price. Even in a best-case scenario this would result in a hefty 66% price erosion over the

space of four years, assuming that the MFN and reimbursed price are not reassessed annually.

Feasibility of MFN Post-Trump

The clause that allows MFN to take effect is the ability under Medicare to pilot innovative pricing programs. Whether this constitutes a pilot program or not will be subject to litigation most likely. Only Medicare Part B can effectively participate in this EO, which is similar in scope to the original announcement when he first tried to do this back in 2019. While the EO was crafted to be a pilot in order to survive legal challenge, it is hard to predict if it will.

Another impediment could be President-Elect Joseph R. Biden, who has publicly stated that he will reverse many, if not all of Trump's EOs. However, the MFN rule in some form is popular and aligned with similar initiatives from both Democrats and Republicans, including H.R. 3 and a desire to curb drug prices generally among Democrats.

However, Biden has said he supports government direct negotiation, and though less concrete, Biden's plan intends to stop "runaway" drug prices, particularly those for medicines not facing any competition, and reduce drug costs by nixing the current exception allowing drug companies to avoid negotiating with Medicare. Biden seeks to leverage the negotiating power of Medicare when determining drug prices, and as detailed on his campaign website, Biden has expressed support for previous legislative efforts to benchmark drug prices against those found in economically similar countries around the world. It is quite possible that even if Trump's proposals fail, that they set the basis for Biden to achieve similar results on international reference pricing by normalizing the approach, as well as set the stage for even further pricing action as well, creating even more pressure on the industry.

Belgium's Budget Secretary Faces Backlash for Tweeting Confidential COVID-19 Vaccine Prices

Date: December 21, 2020 | Country: BELGIUM | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #pfizer #biontech #moderna #astrazeneca #oxford #sanofi #glaxosmithkline #curevac #covid-19 #vaccine #bleeker #ec

PRICENTRIC BRIEF:

- Belgian Secretary of State for Budget and Consumer Affairs Eva De Bleeker is under scrutiny for posting in a since-deleted tweet the prices for COVID-19 vaccines and the number of doses Belgium intends to purchase
- The tweet listed the prices and the variation between manufacturers, but EVERSANA has chosen to respect the presumed confidentiality of the agreement at this time until there is more clarity surrounding the pricing of the vaccines
- The European Commission, which reaffirmed that these prices are to remain private due to commercial confidentiality agreements, has signed contracts with AstraZeneca, Sanofi/GSK, Janssen, BioNTech and Pfizer, CureVac, and Moderna, and last week wrapped exploratory talks with Novavax

THE DETAILS

BRUSSELS, Belgium – Belgian Secretary of State for Budget and Consumer Affairs Eva De Bleeker is under scrutiny for posting in a since-deleted tweet the prices for COVID-19 vaccines and the number of doses Belgium intends to purchase.

Last week, the European Commission wrapped exploratory talks with Novavax regarding the purchase of its COVID-19 vaccine candidate, NVX-CoV2373. The contract would allow European Union (EU) Member States to purchase 100 million doses of the vaccine, with the option to purchase 100 million more.

Already the Commission has signed contracts with AstraZeneca (AZ), Sanofi-GlaxoSmithKline (GSK), Janssen, BioNTech and Pfizer, CureVac, and Moderna. Member States have the option to use these vaccines or donate them to lower- and middle-income countries or redirect the doses to other European countries.

Belgium reportedly intends to purchase over 33 million vaccines, at a total cost of €279 million. The now deleted tweet listed the prices and the variation between manufacturers, but EVERSANA has chosen to respect the presumed confidentiality of the agreement at this time until there is more clarity surrounding the pricing of the vaccines.

The deals surrounding these vaccines were to remain private, with the European Commission saying it cannot disclose prices due to commercial confidentiality agreements.

De Bleeker was summoned forward to Belgium's Chamber to explain why she tweeted the prices, violating Europe's confidentiality clause. As reported by Belgium's HLN, the Secretary stated, "One of the pillars of my policy is transparency and I have been a bit too transparent, perhaps. I emphasize that my attitude does not endanger anything. The vaccines are ready, they are coming, the money has been provided for them."

Price transparency is already a hot button issue, especially in Europe, where efforts to disclose prices have been gaining more traction in recent years. The European Commission has not commented but reaffirmed prices for the vaccines are to remain confidential.

Additionally, Pfizer, who with BioNTech is behind one of the vaccine frontrunners, BNT162b2, called the move by De Bleeker a breach of confidentiality. Elisabeth Schraepen, Pfizer's spokesperson for the Benelux told Belgian daily Le Soir, "These prices are covered by a confidentiality clause in the contract with the European Commission."

Fetcroja, Zavicefta First Antimicrobials Selected for UK's AMR "Subscription-Style" Payments

Date: December 21, 2020 | Country: UNITED KINGDOM | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #antimicrobialresistance #dhsc #hta #nhs #nice #pfizer #shionogi #subscriptionpayments

PRICENTRIC BRIEF:

- NHS England and Improvement, the National Institute for Health and Care Excellence (NICE), and the Department of Health and Social Care (DHSC) have selected Shionogi's Fetcroja (cefiderocol) and Pfizer's Zavicefta (avibactam) as the first antimicrobial drugs to be purchased under the United Kingdom's "subscription-type" payment model
- Over the next year, NICE will evaluate these two medicines, its conclusions informing the subscription payment price each company will get for their respective products, and Fetcroja and Zavicefta are anticipated to be made available to patients under the subscription model from early 2022
- This initiative is part of the UK's 20-year vision for AMR, which outlines developing and testing "new models for national purchasing that de-link the price paid for antimicrobials from the volumes sold, using a NICE led healthcare technology assessment to support robust stewardship," according to the plan

THE DETAILS

LONDON, United Kingdom – NHS England and Improvement, the National Institute for Health and Care Excellence (NICE), and the Department of Health and Social Care (DHSC) have selected Shionogi's Fetcroja (cefiderocol) and Pfizer's Zavicefta (avibactam) as the first antimicrobial drugs to be purchased under the United Kingdom's "subscription-type" payment model.

The NHS has taken the lead on tackling antimicrobial resistance (AMR), when microorganisms develop defenses against antimicrobial drugs. The selection of Fetcroja and Zavicefta marks its latest milestone on setting up "subscription-style" payments to date, this new model serving to incentivize investment and secure a pipeline of future treatments that help combat AMR.

Fetcroja is authorized for treating infections due to aerobic Gram-negative organisms in adults with limited treatment options, whereas Zavicefta is a combination antimicrobial for treating multiple infections, including intra-abdominal and urinary tract infections, as well as hospital-acquired pneumonia.

Over the next year, NICE will evaluate these two medicines, its conclusions informing the subscription payment price each company will get for their respective products, and Fetcroja and Zavicefta are anticipated to be made available to patients under the subscription model from early 2022.

This initiative is part of the UK's 20-year vision for AMR, which outlines developing and testing "new models for national purchasing that de-link the price paid for antimicrobials from the volumes sold, using a NICE led healthcare technology assessment to support robust stewardship," according to the plan.

Essentially, the idea is to move away from paying for individual packs of antimicrobials, instead making annual payments based on health benefits to patients and value to the NHS.

EVERSANA's Europe and Asia-Pacific Vice-President Mike Ryan on Europe's New Pharmaceutical Strategy

Date: December 10, 2020 | Region: EU28, EUROPE | Type: Policy | Keywords: #clinicaltrials #commercialization #covid19 #dataandanalytics #digitalmedic

PRICENTRIC BRIEF:

- In late November, the European Commission announced the adoption of its Pharmaceutical Strategy for Europe, which aims to strengthen the European Health Union while ensuring affordable patient access across the entire European Union and supporting sustainable innovation for pharmaceutical industries.
- Highlights of the Strategy include encouraging greater incorporation of health technology assessment (HTA) requirements in the design of clinical trials, pushing for more affordable pricing, and making patient data more accessible, among other measures
- According to Mike Ryan, EVERSANA's Executive Vice-President, Europe and Asia-Pacific, "When the new Pharmaceutical Strategy for Europe begins its implementation phase in 2021, pharmaceutical companies will have the opportunity to reach broader markets more efficiently and to develop new commercialization strategies focused on patient adherence"

THE DETAILS

The original post can be found here.

In late November, the European Commission announced the adoption of a new healthcare plan – the Pharmaceutical Strategy for Europe. This plan aims to strengthen the European Health Union while ensuring affordable patient access across the entire European Union and supporting sustainable innovation for pharmaceutical industries.

What's Changing, and Why?

Until now, patient access and health data collection has been hindered by increasing drug development costs and, subsequently, pricing, as well as inconsistent drug availability across the European Union (EU). The onset of COVID-19 further emphasized the need to improve patient access, drug affordability, competitive pricing, and overall crisis preparedness and response in the EU healthcare system. In particular, the EU will encourage greater incorporation of health technology assessment (HTA) requirements in the design of clinical trials and subsequent closer collaboration between HTA authorities. The EU is advocating greater consistency in the data requirements for HTA approvals in all member states.

This urgent push for affordable pricing will, the EU believes, contribute to increased competition among pharmaceutical companies in the EU healthcare system. As competition escalates, especially between generic and biosimilar drugs, pharma companies will need to meet heightened standards in HTAs and efficacy as well as supply chain demands.

The EU has recognized that it needs to create accessible patient data across all EU countries whilst ensuring its existing standards of guarding the confidentiality of patient data. The Pharmaceutical Strategy for Europe is committed to creating a database to help stakeholders in healthcare provision, including pharma companies, make better decisions in developing solutions to health issues that are critical to all EU citizens.

Additionally, the EU has recognized the importance of digital solutions in order to help ensure that patients and healthcare systems can continuously evaluate the efficacy of therapies and ensure that patients are benefiting from a multifactorial approach to healthcare.

Opportunity for Pharma to Innovate New Commercialization Models

When the new Pharmaceutical Strategy for Europe begins its implementation phase in 2021, pharmaceutical companies will have the opportunity to reach broader markets more efficiently and to develop new commercialization strategies focused on patient adherence.

The plan specifically addresses the need to provide affordable medication to patients in the areas of antimicrobial resistance, cancer and rare diseases whilst ensuring patient privacy and environmental safety remain priorities for pharma companies.

Now more than ever, pharma companies in the EU market need to consider the following:

- How will they choose a commercial strategy that will provide efficient, synchronous, targeted outcomes for patients and providers across all EU countries?
- What types of digital solutions and technologies can support their overall commercial strategy and collect essential health economic data?
- How will their commercial strategy allow them to quickly and safely introduce their treatment to the global market?

To remain competitive, pharma companies need to decide how they're going to align their commercialization efforts with Europe's new pharmaceutical strategy. By beginning this process now, pharma companies can ensure they remain relevant and do not fall behind in adopting digital technologies and commercial strategies that improve treatment efficacy and adherence for patients across the EU.

About the Author

With more than 25 years of experience in the life science industry, Mike Ryan has held global leadership positions in both clinical development and life-sciences software companies. Given this experience, he is highly experienced in the use of technology and understands its impact in simplifying the process of developing and delivering novel therapies and making them more accessible to patients around the world. He has worked with many biotech and pharmaceutical companies to develop clinical pathways that deliver upon the ultimate commercial goals required to ensure success for all stakeholders. Mike speaks at many global industry events to promote the idea of innovation in healthcare and to encourage a greater level of partnership between healthcare stakeholders.

Spain's Revalmed-SNS Network to Include Economic Evaluations in Therapeutic Positioning Reports

Date: December 1, 2020 | Country: SPAIN | Region: EUROPE | Type: HTA | Keywords: #aemps #costeffectivenessthresholds #economicmodeling #innovation #oncology #pricingandreimbursement

PRICENTRIC BRIEF:

- Patricia Lacruz, Director-General of Basic Portfolio of Services of Spain's National Health System (SNS) and Pharmacy announced that Spain will be following a new economic model for evaluating innovative medicines
- The initiative, Revalmed-SNS, will include economic evaluations in Spain's Therapeutic Positioning Reports (TPRs), which will be fundamental for pricing and reimbursement negotiations going forward
- It will take no more than 90 days to publish a TPR, which will include a new drug's therapeutic position, clinical benefit, safety, and therapeutic alternatives, all in comparison to already-reimbursed medicines, and the drug under assessment will be given a score and ultimately a recommendation or rejection from the Revalmed-SNS committee

THE DETAILS

MADRID, Spain – Patricia Lacruz, Director-General of Basic Portfolio of Services of Spain's National Health System (SNS) and Pharmacy announced that Spain will be following a new economic model for evaluating innovative medicines.

The initiative, Revalmed-SNS, will include economic evaluations in Spain's Therapeutic Positioning Reports (TPRs), which will be fundamental for pricing and reimbursement negotiations going forward.

Spanish industry experts recently suggested that TPRs could potentially help streamline local drug evaluation, following a qualitative study that leaned in favor of the notion. The experts explained that hospital reports and similar documents at the regional level could be completed in a more agile way if TPRs were used as a reference, and so reasoned that they could be used as a tool to facilitate access to new drugs by accelerating the evaluated process.

Revalmed-SNS will be comprised of a therapeutic evaluation group, an economic evaluation group, and therapeutic area specialists. In addition, as Lacruz previously mentioned, the Basic Portfolio of SNS and Hospital Services, the Spanish Medicines Agency (AEMPS), and Spain's autonomous communities themselves will be involved.

It will take no more than 90 days to publish a TPR. The TPRs will include a new drug's therapeutic position, clinical benefit, safety, and therapeutic alternatives, all in comparison to already-reimbursed medicines. Each drug will then be given a score.

Through TPRs, Spain seeks to establish a cost-effectiveness threshold. The Spanish Society of Hospital Pharmacy (SEFH) will contribute to this methodology by reviewing published evaluations, and Spain will consider budgetary impact and target populations.

The 90-day process will be completed in three phases. First, stakeholders, including scientific societies, patient groups, and companies, will offer their expert opinion. Then, Revalmed-SNS' therapeutic and economic evaluation groups will review the TRP.

Finally, the TPR will be discussed by Revalmed-SNS at its monthly meeting, at which point committee members will make their recommendation.

The more stringent use of TPRs and economic models is one of a handful of initiatives announced by Lacruz earlier this year at the meeting of the Spanish Pharmaceutical Industry at the International University of Menendez Pelayo in September.

Through this initiative, which includes biosimilar and generic promotion as well as remodeling the reference price system, Spain seeks to "make access to medicines sustainable for funders and affordable for payers," said Lacruz.

Italian Regions Propose Amendments to Budget Law for 2021

Date: December 7, 2020 | Country: ITALY | Region: EUROPE | Type: Policy | Keywords: #biosimilar #budget #funds #generic #italy #law #legislation #payback #policy

PRICENTRIC BRIEF:

- The Italian regions have published a document proposing amendments regarding pharmaceutical governance, spending ceilings and payback
- The proposed amendments act as updates to the Ministry of Health's 2018 Drug Governance, relating to Legislative Decree art. 80 and 81
- The amendments follow news that Italy's Parliamentary Budget Office has estimated that the country's new pharmaceutical spending caps could save as much as EUR 470 million in 2020

THE DETAILS

ROME, Italy - The Italian regions have published a document proposing amendments regarding pharmaceutical governance, spending ceilings, and payback.

The proposed amendments act as updates to the Ministry of Health's 2018 Drug Governance, relating to Legislative Decree art. 80 and 81.

The amendments follow news that Italy's Parliamentary Budget Office has estimated that the country's new pharmaceutical spending caps could save as much as EUR 470 million in 2020.

Speaking at a hearing, the Office explained that the ceilings will "lead to a reduction in the overrun of expenditure for direct purchases of drugs and a consequent decrease in the sums owed by pharmaceutical companies to the NHS (so-called pay-back), estimated at around 400 million with reference to 2020, to which a further 70 million must be added for the increase in health needs decided by the budget bill (on which the ceiling was calculated)."

Italy almost always exceeds its budget. Although most health systems were severely impacted by the COVID-19 pandemic, in the first four months of the year Italy's drug spending surpassed the budget by €1.3 billion.

The document is broken down into the below categories and areas of reform, but the full text can be found here.

Review of the National Pharmaceutical Handbook

The proposal notes that the Italian Medicines Agency (Aifa) should promptly verify the presence in the National Pharmaceutical Handbook (PFN) of therapeutically equivalent drugs admitted for reimbursement by the national health service (SSN) with differentiated prices, promoting interventions aimed at mitigating such differences.

Equivalent Drugs and Transparency Lists

As it stands, lists need to be prepared and updated monthly by Aifa based on reimbursement payable by the NHS "… up to the competition of the lowest price of a corresponding product available in the normal regional distribution cycle," to take into account all medicines for which there are price differences, regardless of the presence or less than patent coverage. The document stresses that it is a priority that AIFA defines and publishes the rules adopted for the inclusion of drugs on the transparency list.

Biosimilar Legislation

The regions have suggested that AIFA should start information campaigns to raise awareness of the use of generics, and the appropriate use of biological and biosimilar drugs. Further, in order to facilitate access to care and promote greater competition, the regions have suggested that it is necessary to intervene with a review of the current biosimilar and generic regulatory provisions.

Aifa & Identifying Therapeutic Equivalents

The regions suggest that in the context of direct purchases, there is still too low a share of purchases under competition, as well as a significant variability between the regions. As such, the regions believe it is necessary that Aifa makes public the evaluation requests made by the regions, including the submission date.

Patent Linkage

The document suggests that it is necessary to make a decision regarding the distinction between "process patents" or "use patents" in regard to the marketing of generic and biosimilar medicines, as the issue generates numerous controversies for the purposes of preparation of tenders by the purchasing centers and in the preparation phase of the "transparency lists".

Drug Value Evaluation

Article 3, Paragraph 3 of the new inter-ministerial price decree of 20 July 2020 asks that the Scientific Technical Commission analyses both the clinical value of the drug and the added therapeutic value compared to the drugs indicated as comparative reference medicines.

As per the new legislation, to negotiate a drug's price, a drugmaker must provide the Italian Medicines Agency (AIFA) with a series of documents, firstly 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 system is comparable to that of France or Germany's, in which they give the drug in question a benefit rating.

Innovative Drugs

For conditional innovation drugs, at least one reassessment will be mandatory 18 months after its grant. In the presence of evidence that disproves its recognition or reduced its effect, its innovativeness cannot be confirmed, and the related benefits will be removed, with the consequent start of a new negotiation of the price and of the reimbursement conditions.

Essentially, the permanence of the innovative status attributed to a drug will be reconsidered if evidence emerges that justifies the revaluation.

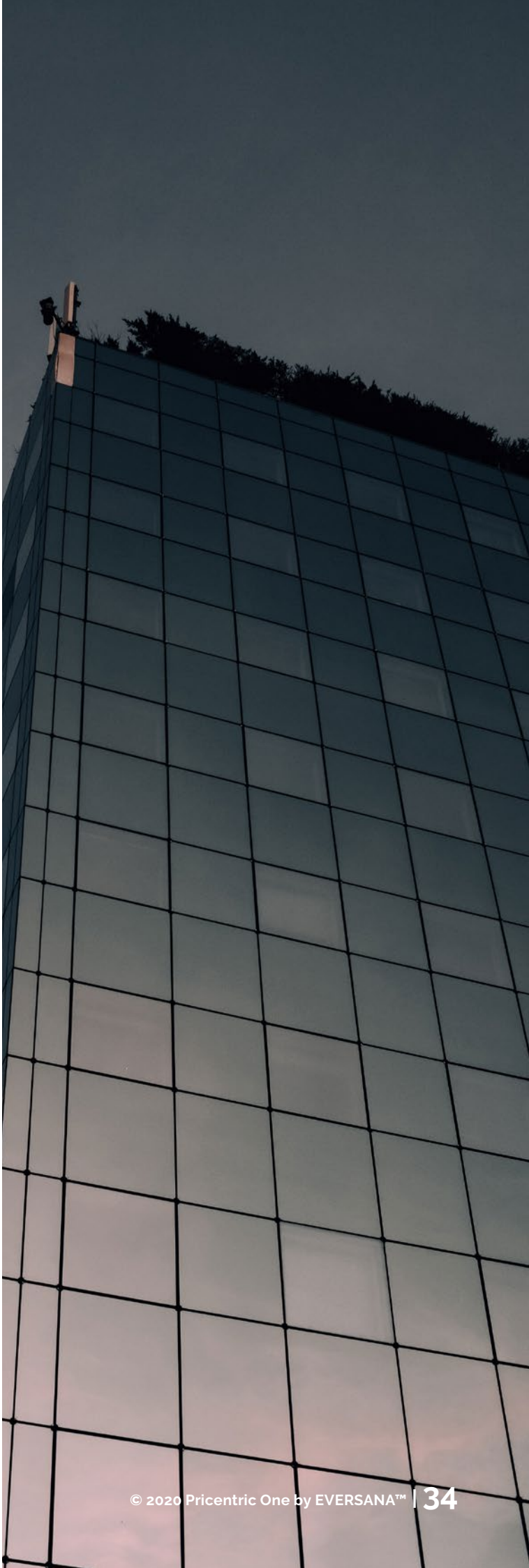
Horizon Scanning

The proposal states that information available from the European Medicines Agency (EMA) is necessary for horizon scanning, and as such must be made available to the regions to allow the correct and timely planning of regional pharmaceutical governance.

Drug Pricing

In line with what is indicated in the Decree published in July, two principles must be reaffirmed:

- Drugs with the same value, or with the same therapeutic value, must be charged with the SSN equal
- Higher reimbursement SSN price than therapeutic alternatives may only be recognized for drugs that have demonstrated an advantage therapeutic, in terms of clinical outcomes such as survival, quality of life, the symptom control, reduction of clinically relevant toxicity



Because of this, the regions note that both the value of the drug and its added value must be disclosed by the Scientific Technical Commission.

Non-reimbursed Drugs

As it stands, the Interministerial Decree of 20 July 2020 focuses on band C of drugs to bring them back to negotiation. However, in the case of a non-agreement, the drug will be (or will remain) classified in class C with a non-negotiated price, albeit purchased from hospitals with resources from the SSN.

The regions have decided that this topic requires reevaluation.

Purchase of Drugs at Non-negotiated Prices

Law 648 establishes that if there is no valid therapeutic alternative, the below are payable entirely by the National Health Service:

- Innovative medicines whose marketing is authorized in other states, but not nationally
- Medicines not yet authorized but undergoing clinical trials
- Medicines to be used for a therapeutic indication other than that authorized, included in a special list prepared and periodically updated by the Single Medicines Commission, in accordance with the procedures and criteria adopted by the same

The regions have noted that it is necessary to implement what is indicated in the decree as well as activate one reporting of expenditure related to these drugs, as the modalities of the plan have not yet been defined.

Therapeutic Plans and AIFA Registers

The document stresses the need to maintain Therapeutic Plans (TP) and Aifa registers in a digital manner, eliminating the paper mode which does not allow the collection of information either at the regional or national level.

Further, they want a reflection on the already-established TPs to determine whether a drug should be kept as prescription-only by medical specialists, or if the conditions for prescribing should be transferred to GPs.

Finally, according to the regions, Aifa must facilitate the integration between the data in the Aifa and data from clinical disease registers active in Italy and current health databases.

Payback Disputes

Finally, based on what was reported by Aifa at the hearing of the Health Commission on 4 November, 138 appeals were received against the decision made on payback.

In November, 138 appeals were received against the 2018 Aifa decision, and as such the review procedure was put in progress as requested by the Lazio Regional Administrative Court.

Out of 414 companies impacted by the 2018 shelf, 299 made payments for an amount of 734,439,765 EUR, equal to 70% of the overall "shelf."

Aifa is therefore preparing to evaluate all further written and oral observations that should arrive, after which a new shelf determination will then have to be adopted, replacing the n.128 / 2020, which establishes the new shelf quotas and indicates the possible ways in which who to pay the residual payback. Currently, the rule is: Whoever has paid more can recover the difference.

Minister of Health, Roberto Speranza, hopes the Budget Law will address the issue of the "payback affair."

Already the government is seeking a way to adjust ceilings through the National Reform Program, calling for "reflection" and "reshaping" on pharmaceutical spending ceilings. Additionally, Italy seeks to intervene in this area through the Health Pact 2019-2021.

The pharmaceutical industry in Italy has often fought with Italy over payback and spending ceilings, even entering long litigation.

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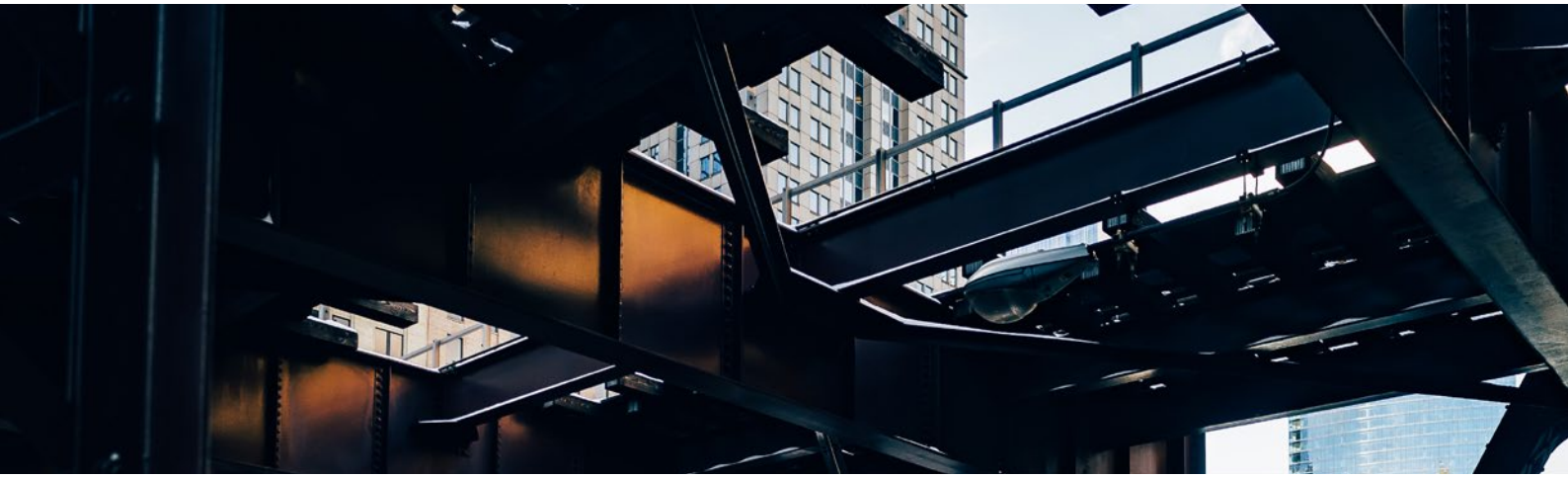
Japan's First Off-Year Re-Pricing to Impact 70% of All NHI-Listed Medicines



Date: December 18, 2020 | Country: JAPAN | Region: ASIA & SOUTH PACIFIC | Type: Price Changes | Keywords: #mhlw #nhi #offyearrepricing #policy #pricediscrepancies #regulation

PRICENTRIC BRIEF:

- Japan's government has decided to move ahead with off-year re-pricing for the first time in April 2021 for products with national health insurance (NHI) and market price gaps above 5%, or 70% of all listed drugs and 60% of innovative medicines in Japan
- Off-year re-pricing was a biannual practice in Japan before the government decided to implement it yearly, to take place in April after prices are surveyed in September
- As with previous years, the average discrepancy between NHI and market prices for this year's re-pricing was around 8%, according to the September 2020 drug survey, however, officials are only tweaking the prices of medicines above the 5% threshold, sparing those with price discrepancies below this percentage

THE DETAILS

TOKYO, Japan – Japan's government has decided to move ahead with off-year re-pricing for the first time in April 2021 for products with national health insurance (NHI) and market price gaps above 5%, or 70% of all listed drugs and 60% of innovative medicines in Japan.

Off-year re-pricing was a biannual practice in Japan before the government decided to implement it yearly, to take place in April after prices are surveyed in September.

Multiple industry groups and stakeholders pleaded against enacting off-year re-pricing this year due to the impact of the COVID-19 pandemic on the health system as a whole, preferring the government not to do away with off-year re-pricing entirely but delay it until things are again running as normal.

Notably, the Pharmaceutical Manufacturers' Association Federation of Japan (FPMAJ) urged the government to stall its plan because of major delays experienced in price negotiations between wholesalers and medical institutions, frontline healthcare providers are already burdened by the virus, and the industry is doing its best to ensure stable prices, despite COVID-19.

However, recently re-appointed Minister of Health, Labor, and Welfare Norihisa Tamura vowed that the Ministry will investigate the impact of off-year re-pricing on pharmaceutical companies and medical institutions, with a focus on the margins between NHI prices and market prices that have become a source of income for medical institutions.

As with previous years, the average discrepancy between NHI and market prices for this year's re-pricing was around 8%, according to the September 2020 drug survey. To mitigate the impact of re-pricing, officials sought to only tweak the prices of medicines above either a 4% or 6% threshold, before settling on 5%.

This go at off-year re-pricing is Japan's first attempt at annual re-pricing of medicines in Japan, and a government survey was conducted this past September to find major discrepancies between NHI and market prices. NHI prices were to be implemented based on results from a survey of 67% of wholesaler offices and half the number of healthcare institutions.

Yescarta Nears Approval in Japan

Date: December 7, 2020 | Country: JAPAN | Region: ASIA & SOUTH PACIFIC | Type: Drug Approval |
Keywords: #cartcelltherapy #cellandgenetherapy #daiichisankyo #gilead #kite #mhlw #pafsc #regenerativemedicine

PRICENTRIC BRIEF:

- Yescarta (axicabtagene ciloleucel) has received a nod for approval from Japan's Pharmaceutical Affairs and Food Sanitation Council's (PAFSC) subcommittee on regenerative medicines, biologics, and biotechnologies, reported Pharma Japan
- At the end of March this year, Daiichi Sankyo submitted a New Drug Application (NDA) to Japan's Ministry of Health, Labor, and Welfare (MHLW) for Yescarta for the treatment of adult patients with relapsed/refractory (R/R) diffused large B-cell lymphoma (DLBCL) and related lymphomas
- In 2017, Daiichi Sankyo obtained exclusive development, manufacturing, and commercialization rights for Yescarta in Japan from Kite, which is now a part of Gilead

THE DETAILS

TOKYO, Japan – Yescarta (axicabtagene ciloleucel) has received a nod for approval from Japan's Pharmaceutical Affairs and Food Sanitation Council's (PAFSC) subcommittee on regenerative medicines, biologics, and biotechnologies, reported Pharma Japan.

In 2017, Daiichi Sankyo entered into a strategic partnership with Kite Pharma – now part of Gilead – to acquire exclusive development, manufacture, and commercialization rights for Yescarta in Japan.

At the end of March this year, Daiichi Sankyo submitted a New Drug Application (NDA) to Japan's Ministry of Health, Labor, and Welfare (MHLW) for Yescarta for the treatment of adult patients with relapsed/refractory (R/R) diffused large B-cell lymphoma (DLBCL) and related lymphomas.

The PAFSC committee nod applies to Yescarta for four aggressive types of relapsed/refractory (R/R) B-cell lymphomas including diffuse large B cell lymphoma (DLBCL); primary mediastinal B-cell lymphoma (PMBCL); transformed follicular lymphoma (TFL); and high-grade B cell lymphoma (HGBL).

Specifically, patients with the aforementioned cancers will be eligible for treatment with Yescarta if they have not been previously treated with CAR T-cell therapy, are eligible for autologous stem cell transplant (ASCT), have failed at least two cycles of chemotherapy in new cases or one cycle of chemotherapy in recurrent cases, their disease is recurrent after ASCT, or they are ineligible for ASCT.

Post-marketing surveillance is mandatory for Yescarta as a term of its approval in Japan. It should be administered at medical facilities with staff who are experts in the field and can manage potential risks associated with Yescarta.

Kymriah First in Japan, No Special Pricing Method for CAR T-Cell Therapy

Rival CAR T-cell therapy Novartis' Kymriah (tisagenlecleucel) was approved in Japan in May 2019 for the treatment of CD19-positive relapsed/refractory (r/r) B-cell acute lymphoblastic leukemia (ALL) for patients up to 25 years old and CD-19-positive r/r diffuse large B-cell lymphoma (DLBCL).

Kymriah was approved at a price (public price, VAT included) of 33,493,407 yen. As Japan has no specific rules for the pricing of cell and gene therapies – they're categorized as regenerative medicines – Japan's Chuikyo applied existing cost-based method of drug pricing to set the national health insurance (NHI) price for Kymriah.

Initially, Kymriah earned a 35% utility premium and a 10% marketability premium; however, the premium rate was slashed by 80% to just 9% under a rule introduced last year for the cost-based pricing method, which reduces launch premium rates based on the ratio of disclosed costs.

Gilead, Kite Bags Conditional Marketing Authorization for Tecartus in Europe

Date: December 16, 2020 | Country: BELGIUM | Region: EU28, EUROPE | Type: Drug Approval | Keywords: #cellandgenetherapy #conditionalapproval #ema #europeancommission #gilead #kite #primedesignation

PRICENTRIC BRIEF:

- The European Commission has granted conditional marketing authorization for Gilead/Kite's CAR T therapy Tecartus (brexucabtagene autoleucel) for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor

- Conditional marketing authorization was granted to Tecartus based on the Phase 2 open-label ZUMA-2 pivotal trial in patients with relapsed or refractory MCL in which an overall response rate (ORR) of 93% was demonstrated, with 67% of patients achieving a complete response

- Previously, Tecartus received Priority Medicines (PRIME) designation from the European Medicines Agency (EMA)

THE DETAILS

BRUSSELS, Belgium – The European Commission has granted conditional marketing authorization for Gilead/Kite's CAR T therapy Tecartus (brexucabtagene autoleucel) for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor.

Conditional marketing authorization was granted to Tecartus based on the Phase 2 open-label ZUMA-2 pivotal trial in patients with relapsed or refractory MCL who had previously received anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 antibody therapy and a BTK inhibitor.

An overall response rate (ORR) of 93% was demonstrated in ZUMA-2, with 67% of patients achieving a complete response, explained Kite.

Currently in Europe, an estimated 7,400 people are diagnosed with MCL each year. Those with relapsed or refractory MCL after two or more lines of systemic therapy, including a BTK inhibitor, typically have a poor prognosis, with a median overall survival (OS) of six to 10 months.

Professor John G. Gribben, Consultant Hematologist and Medical Oncologist at Barts and The London NHS Trust, London, noted, "Significant gaps in treatment remain for patients with mantle cell lymphoma who progress following initial therapies. The availability of this first cell therapy for relapsed or refractory mantle cell lymphoma, following at least two lines of systemic therapy including a BTK inhibitor, provides an important option for patients in Europe."

Ken Takeshita, MD, Kite's Global Head of Clinical Development, added, "We are proud our second cell therapy has been approved for use in Europe, and I extend my thanks to the patients who participated in the clinical trial and their families and caregivers, clinical researchers, regulators and dedicated colleagues at Kite who helped make this approval possible for patients living with relapsed or refractory mantle cell lymphoma."

In Europe, conditional marketing is valid for one year but can be either extended or converted into marketing authorization after further data are submitted. Previously, Tecartus received Priority Medicines (PRIME) designation from the European Medicines Agency (EMA).

Canada Approves Novartis' SMA Gene Therapy Zolgensma

Date: December 17, 2020 | Country: CANADA-ONTARIO | Region: NORTH AMERICA | Type: Drug Approval | Keywords: #celland-genetherapy #healthcanada #novartis

PRICENTRIC BRIEF:

- Health Canada has approved Novartis' gene therapy Zolgensma (onasemnogene abeparvovec) for the treatment of pediatric patients with 5q spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene and 3 or fewer copies of SMN2 gene; or infantile-onset SMA

- The approval was based on efficacy and safety data from both completed and ongoing clinical trials of Zolgensma in pediatric patients with infantile-onset SMA and two copies of the SMN2 gene, and presymptomatic genetically diagnosed SMA and two or three copies of the SMN2 gene

- Novartis' Marazzi said that the company will continue to work collaboratively with the pan-Canadian Pharmaceutical Alliance, provinces, and territories to make sure those who benefit most from Zolgensma can access it

THE DETAILS

OTTAWA, Canada – Health Canada has approved Novartis' gene therapy Zolgensma (onasemnogene abeparvovec) for the treatment of pediatric patients with 5q spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene and 3 or fewer copies of SMN2 gene; or infantile-onset SMA.

The approval was based on efficacy and safety data from both completed and ongoing clinical trials of Zolgensma in pediatric patients with infantile-onset SMA and two copies of the SMN2 gene, and presymptomatic genetically diagnosed SMA and two or three copies of the SMN2 gene.

Each year in Canada, approximately one in 10,000 babies are born with SMA.

Dr. Nicolas Chrestian, Chief of Pediatric Neurology, who specializes in neuromuscular disorders at Quebec City's Centre Hospitalier Mère Enfant Soleil, commented, "When I first started diagnosing SMA, I couldn't have imagined that we would see such scientific advancements. Zolgensma offers, in a single dose, the possibility of halting the progression of this degenerative condition that can rob children of regular developmental milestones."

Andrea Marazzi, Country Head, Novartis Pharmaceuticals Canada, said, "Today's announcement about the Canadian approval of Zolgensma is a significant milestone in our journey to reimagine medicine by changing the treatment paradigm for children with SMA.

"Our commitment to the SMA community truly comes to life when those that could benefit most from Zolgensma can access it. This is why we continue to work collaboratively with the pan-Canadian Pharmaceutical Alliance, provinces, and territories to make this happen as quickly as possible," concluded Marazzi.

CMED Sets Maximum Prices for Zolgensma, Luxturna, Brazil's First Gene Therapies

Date: December 9, 2020 | Country: BRAZIL | Region: SOUTH AMERICA | Type: Pricing & Reimbursement | Keywords: #anvisa #cellandgenetherapy #cmed #maximumsellingprices #novartis

PRICENTRIC BRIEF:

- At the 6th Extraordinary Meeting of the Medicines Market Regulation Chamber's (CMED) Technical-Executive Committee, the agency authorized maximum selling prices for Novartis' gene therapies, Zolgensma (onasemnogene abeparvovec) and Luxturna (voretigene neparvovec)—however, the prices have not yet been announced
- CMED's decision to set the price for these gene therapies, Brazil's first two ever, was called "unprecedented" by Brazil's National Sanitary Surveillance Agency (ANVISA), and Novartis still has time to appeal
- In August, Luxturna was approved for the treatment of vision loss due to hereditary retinal dystrophy and Zolgensma for the treatment of pediatric patients up to two years old diagnosed with type 1 SMA with biallelic mutations in the SMN1 gene or up to three copies of another gene known as SMN2

THE DETAILS

BRASILIA, Brazil – At the 6th Extraordinary Meeting of the Medicines Market Regulation Chamber's (CMED) Technical-Executive Committee, the agency authorized maximum selling prices for Novartis' gene therapies, Zolgensma (onasemnogene abeparvovec) and Luxturna (voretigene neparvovec).

Now, Zolgensma can be made available for spinal muscular atrophy (SMA) patients aged two years and under and Luxturna for the treatment of vision loss due to hereditary retinal dystrophy.

CMED's decision to set the price for these gene therapies, Brazil's first two ever, was called "unprecedented" by Brazil's National Sanitary Surveillance Agency (ANVISA). Novartis still has the possibility to appeal to CMED regarding the prices it set.

The prices for these two gene therapies have not yet been announced.

August of this year saw Brazil approve its first gene therapy, Luxturna, however, its commercialization remained dependent on ANVISA assessment of its therapeutic capacity and subsequent approval. All in all, it took 232 business days from submission until ANVISA said yes to Luxturna.

Shortly after Luxturna secured approval, ANVISA announced it approved Zolgensma for the treatment of pediatric patients up to two years old diagnosed with type 1 SMA with biallelic mutations in the SMN1 gene or up to three copies of another gene known as SMN2.

Prior to ANVISA's final decision, both Luxturna and Zolgensma collected nods from the Brazilian Technical Commission of Biosafety (CTNBio), the body responsible for evaluating biosafety of Genetically Modified Organisms (GMOs) in Brazil.

With Zolgensma, ANVISA concluded its benefits outweighed any risks, however, because it is an innovative gene therapy, an exceptional record was approved, meaning that additional studies must be carried out by the company to confirm its long-term effectiveness and safety.

Brazilian President Jair Bolsonaro moved import tax rates to zero for Zolgensma before it secured ANVISA approval. Without zero import tax, Zolgensma would have been subject to a 4% tax rate—or, an additional USD 80,000, according to the Brazil Report.

At the time, former directors of ANVISA and the Ministry of Health warned against Bolsonaro's decision, as it could set a negative precedent for the future of these drugs, which are still very new to the Brazilian market.

Amgen Bags FDA Approval for Rituximab Biosimilar, Riabni

Date: December 18, 2020 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Biosimilar | Keywords: #amgen #drugapproval #fda #rituxan #ruxience #truxima

PRICENTRIC BRIEF:

- The U.S. Food and Drug Administration has approved Amgen's rituximab biosimilar Riabni – referencing Rituxan (rituximab)
- Riabni is approved for the treatment of adult patients with Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis), and Microscopic Polyangiitis (MPA)
- Riabni will be available in the U.S. in January 2021, at a Wholesale Acquisition Cost (WAC) pf $716.80 per 100 mg and $3,584.00 per 500 mg single-dose vial, 23.7% less than the reference product, according to Amgen

THE DETAILS

WASHINGTON, D.C., The United States – The U.S. Food and Drug Administration has approved Amgen's rituximab biosimilar Riabni – referencing Rituxan (rituximab) – for the treatment of adult patients with Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis), and Microscopic Polyangiitis (MPA).

In a randomized, double-blind, comparative clinical study evaluating the efficacy, pharmacokinetics (PK), pharmacodynamics (PD), safety, tolerability and immunogenicity of Riabni compared to Rituxan in subjects with grade 1, 2, or 3a follicular B-cell NHL and low tumor burden, the primary endpoint, an assessment of overall response rate (ORR) by week 28, was within the prespecified margin for Riabni compared to Rituxan, showing clinical equivalence.

Murdo Gordon, Executive Vice President of GLobal Commerical Operations, Amgen, commented, "The approval of Riabni represents an important milestone across our biosimilar and oncology portfolios."

"Following the proven success of Kanjinti (trastuzumab-anns) and Mvasi (bevacizumab-awwb) in the US marketplace, Riabni reaffirms Amgen's long-term commitment to providing high quality biosimilars that can potentially offer more affordable, effective treatment options for cancer and other serious diseases and that contribute to the sustainability of health care systems," concluded Gordon,

Riabni will be available in the U.S. in January 2021, at a Wholesale Acquisition Cost (WAC) pf $716.80 per 100 mg and $3,584.00 per 500 mg single-dose vial, 23.7% less than the reference product, according to Amgen. Moreover, the WAC for Riabni is 15.2% less than the WAC for rituximab biosimilar Truxima, but the same as Ruxience.

PPRMA 2020

The Pricentric news team attended the virtual broadcast of the 3rd Annual Pharma Pricing, Reimbursement & Market Access 2020 conference and summed up what we learned.

HTA and Decision Making in the Reimbursement of Medicines

PRICENTRIC BRIEF:

- During the virtual broadcast of the 3rd Annual Pharma Pricing, Reimbursement & Market Access 2020 conference, Boxiong Tang, MD, PhD, Sr, Director, Medical Affairs, BeiGene, spoke on why new drugs are failing to gain reimbursement from payers and HTAs
- Tang began by explaining the current environment, noting a huge increase in R&D and a more crowded market, meaning assets must address a wide range of global payer needs
- One size does not fit all, so it is imperative to have a strategic approach to HTAs and it is important to know about fundamental market differences

Keynote Panel Discussion: Regulatory Updates & Development

PRICENTRIC BRIEF:

- Robert Popovian, VP, Government Relations, Pfizer, said transparency is needed in drug price setting in the US, noting that 50 cents in every dollar of drug profit goes to the middle man—He said omitting PBM rebates is the first step
- Popovian concluded that the drug pricing issue is a "wack-o-mole" situation—Perhaps a dozen or two dozen policies are needed to fix the system, to straighten out the drug pricing model
- There was a consensus that value-based contacts are not appropriate for all therapies: Stacey Worthy, Principle Attorney, Sequel Legal, noted, "You would think health disparities would benefit from value-based payment models, but they can actually worsen disparities"

New Drugs Win Regulatory Approval But Increasingly Fail to Gain Reimbursement

PRICENTRIC BRIEF:

- Melva Covington, Vice President, RWD, Ciox Health, spoke on hurdles for new drugs in the way of reimbursement from payers
- More new drugs are winning regulatory approval, but, she said, they are facing mounting difficulty when seeking reimbursement
- She said hurdles include customer willingness to pay, as well as growing market access pressures on costs and demonstration of outcomes, but RWD-related solutions can inform evidence and insight as it relates to decision making

Key Developments In European Market Access

PRICENTRIC BRIEF:

- Neil Grubert, founder of Future of Pharmaceutical Market Access group, spoke on key developments in European market access
- External reference pricing (ERP) is growing, managed entry is slowly building momentum, and pressure for transparency is mounting, from countries like Belgium, Germany, the Netherlands, and France
- Opportunities may involve the use of savings from cost containment to fund innovative medicines, a shift from health technology assessment to health technology management potentially helping to overcome payers' risk aversion, and "beyond the pill" initiatives which could help to foster partnerships with healthcare systems

Payer's Perspective: What Are They Looking For?

PRICENTRIC BRIEF:

- Anna Forsythe, spoke on the payer's perspective on funding new therapies
- Many challenges exist in attempting to explain benefit to payers, Forsythe explained, especially because RCTs are "no longer the gold standard" for HTA

- Forsythe covered a wide number of tactics to use, including early and systematic evidence generation, early value framework and early economic models, "live" systematic literature reviews, comparative effectiveness studies, the use of RWD, and publishing value communications

Different Responses to New Therapies on the EU and US Markets

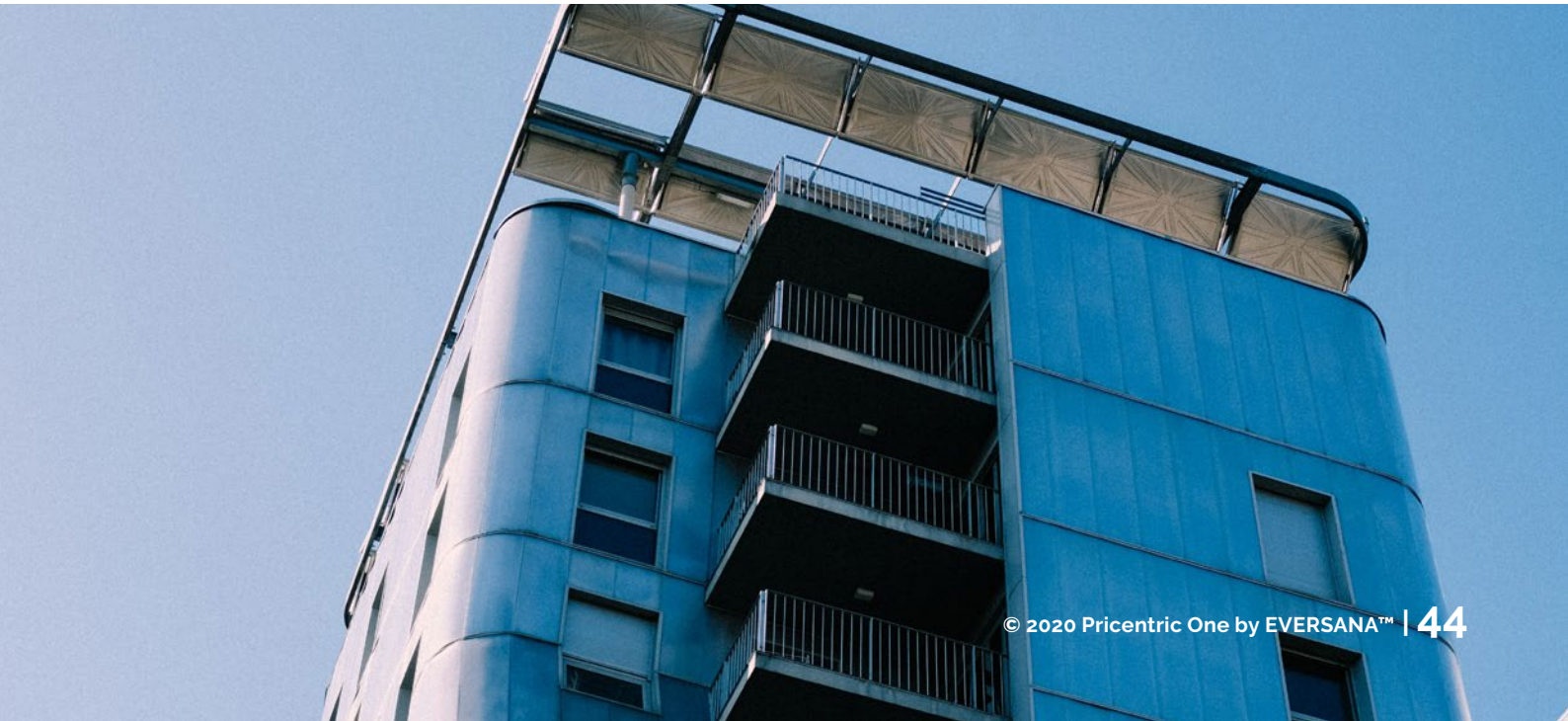
PRICENTRIC BRIEF:

- Anita Burrell recalled that in France, Kymriah, Yescarta, and Luxturna were evaluated by HAS as having 'important' actual clinical benefit because of the focus on clinical effectiveness, disease severity, and rarity as well as unmet medical needs of the disease area
- In comparison, Burrell explained, Germany focuses on the comparative benefits against available treatments and this led to the "unquantifiable benefit" for Glybera, Kymriah, and Yescarta as they used a historical comparison
- In the case of NICE, greater importance is attached to cost-effectiveness analysis, said Burrell—NICE defined a higher ICER threshold for ultra-orphan drugs evaluated under the HST pathway allowing for a higher uncertainty in economic analysis could be acceptable (ex. Strimvelis for ADA-SCID treatment in England)

Challenges and Opportunities in Pharma Pricing

PRICENTRIC BRIEF:

- When asked what will become of the Most Favored Nation executive order signed by President Trump, Richard Liner, Senior Compliance Counsel, Bayer, expressed concerns about constitutional challenges, before even taking into account legal and administrative complexity involved in implementation
- Nanxin Li, Senior Director, Health Economics and Outcomes Research (HEOR), uniQure, added that the executive order could jeopardize the country's position as a leading country in innovation in pharmaceuticals, though it also depends on the drug
- On the subject of point of sale under Medicare Part D, Liner wonders about how they would implement the proposal at the point of sale as it is complicated and agreements with PBMs are hidden—Concerns were also raised about how formulary tiers would be determined



COVID-19 Vaccine Updates

Moderna Agrees to Supply UK With Additional 2M Doses of COVID-19 Vaccine

Date: December 1, 2020 | Country: UNITED KINGDOM | Region: EUROPE | Type: Regulation | Keywords: #agreement #coronavirus #covid-19 #efficacy #moderna #mrna #purchase #vaccine

PRICENTRIC BRIEF:

- Moderna has revealed a new supply agreement with the UK government for an additional two million doses of its COVID-19 vaccine, mRNA-1273
- The agreement follows news that the primary efficacy analysis of the Phase 3 COVE study of the shot conducted on 196 cases indicates a vaccine efficacy of 94.1%, the company announced
- The new agreement entitles the UK to the extra doses by the beginning of March 2021, meaning that the government has now secured seven million doses of mRNA-1273 in total

UK Approves Pfizer's COVID-19 Vaccine, Announces Roll-out For Next Week

Date: December 2, 2020 | Region: EUROPE | Type: Drug Approval | Keywords: #approval #authorization #biontech #covid-19 #pfizer #uk

PRICENTRIC BRIEF:

- The UK's Medicines & Healthcare Products Regulatory Agency (MHRA) has become the first regulatory body in the world to grant approval to a COVID-19 vaccine, following its Emergency Use Authorization of Pfizer and BioNTech's Candidate
- The MHRA's review determined that the vaccine candidate meets the Agency's robust standards of quality, safety, and effectiveness, meaning that it can now move forward with the UK's pre-purchase agreement for 40 million doses by the end of 2021
- The decision, which was based on a rolling submission of the Company's data, marks a "historic" moment in the fight against COVID-19, according to Albert Bourla, Chairman and Chief Executive Officer, Pfizer, who went on to note that the pharma giant is "focused on moving with the same level of urgency to safely supply a high-quality vaccine around the world"

South Korea Inks Deal with AstraZeneca to Buy COVID-19 Vaccine

Date: December 3, 2020 | Country: SOUTH KOREA | Region: ASIA & SOUTH PACIFIC | Type: Regulation | Keywords: #astrazeneca #covid-19 #procurement #purchase #vaccine

PRICENTRIC BRIEF:

- Local media in South Korea has reported that the country has reached a deal with AstraZeneca to purchase its coronavirus vaccine candidate.
- The agreement was allegedly signed on November 27, and South Korea is also nearing agreements with Pfizer and Johnson & Johnson for their respective candidates, according to an unidentified government official
- However, the Korea Disease Control and Prevention Agency (KDCA) said that the Korean news source - JoongAng report - was not the government's official position, but confirmed that it would finalize talks and unveil comprehensive results shortly

Swiss Federal Government Signs Deal with Pfizer for 3M Doses on Approval

Date: December 8, 2020 | Country: SWITZERLAND | Region: EUROPE | Type: Regulation | Keywords: #approval #biontech #contract #council

PRICENTRIC BRIEF:

- The Swiss Federal Government has signed a

contract with Pfizer and BioNTech entitling Switzerland to 3 million doses of the companies' COVID-19 vaccine, assuming the candidate gains approval

- The Pfizer vaccine is expected to require two doses, meaning that the amount would allow 1.5 million people in Switzerland to be vaccinated
- So far, Switzerland has signed contracts with three vaccine manufacturers whose products are close to the finish line; Pfizer/BioNTech, Moderna (around 4.5 million vaccine doses) and AstraZeneca (around 5.3 million vaccine doses), and as it stands all three vaccines are currently going through the approval process at Swissmedic

Israel Triples Order of Moderna's COVID-19 Vaccine Candidate mRNA-1273

Date: December 8, 2020 | Country: ISRAEL | Region: MIDDLE EAST | Type: Regulation | Keywords: #covid19 #healthministry #moderna

PRICENTRIC BRIEF:

- Moderna has expanded its vaccine supply agreement with Israel's Ministry of Health to include an additional 4 million doses of the company's COVID-19 vaccine candidate mRNA-1273
- The updated agreement triples Israel's previous request for 2 million doses of mRNA-1273, providing the health ministry with 6 million doses to vaccine 3 million people
- At the end of November, the company published its primary efficacy analysis of the Phase 3 COVE study of mRNA-1273 conducted on 196 cases, indicating a vaccine efficacy of 94.1%

Switzerland's Army Pharmacy Procures Medical Goods During Pandemic

Date: December 8, 2020 | Country: SWITZERLAND | Region: EUROPE | Type: Regulation | Keywords: #army #covid-19 #foph #pandemic #pharmacy

PRICENTRIC BRIEF:

- The Federal Office of Public Health (FOPH / BAG) published a report of medical goods procured by Switzerland's army pharmacy during the COVID-19 pandemic
- On March 20, 2020, at the start of the pandemic, the army pharmacy was tasked by the Federal Council with procuring important medical goods for the health care system, as a strategy to prevent potential shortages
- The Federal Office of Public Health loaned the army pharmacy enough funds to purchase a guaranteed 180 day security supply of personal protective equipment, medical devices, disinfectants, laboratory accessories and test kits, drugs and vaccines

Belgium Agrees to Purchase of Moderna's COVID-19 Vaccine Through EC

Date: December 8, 2020 | Country: BELGIUM | Region: EUROPE | Type: Regulation | Keywords: #covid-19 #ema #eu #famhp #imc #moderna

PRICENTRIC BRIEF:

- The Federal Agency for Medicines and Health Products (FAMHP) announced Belgium has agreed to purchase Moderna's COVID-19 vaccine candidate through the European Commission's negotiation
- If it receives a marketing authorization, the vaccine will be purchased by Belgium in the amount of 2 million doses—a small sliver of the 80 million doses spelled out in the European contract
- The country's task force for the operationalization of the COVID-19 vaccination strategy presented a plan for rolling out the vaccination program at an extra Interministerial Conference on December 3, 2020

Canada Doubles COVID-19 Vaccine Dose Purchase from Moderna

Date: December 9, 2020 | Country: CANADA-ONTARIO | Region: NORTH AMERICA | Type: Regulation | Keywords: #covid-19 #moderna #vaccine

PRICENTRIC BRIEF:

- Moderna announced that Canada has committed to purchasing an additional 20 million doses of Moderna's vaccine candidate against COVID-19, mRNA-1273, meaning its total commitment now adds up to 40 million doses
- Moderna's delivery schedule is running on time with the potential to distribute the vaccine as early as December if the drugmaker wins regulatory approval this month
- The vaccine doses purchased by Canada are to be shipped from Moderna's European production capacity with its strategic manufacturing partner Lonza in Switzerland, and ROVI in Spain for fill-finish services

Korea to Pre-Purchase COVID-19 Vaccine Candidates for 44 Million People

Date: December 9, 2020 | Country: SOUTH KOREA | Region: ASIA & SOUTH PACIFIC | Type: Regulation | Keywords: #astrazeneca #covax #covid-19 #janssen #moderna #pfizer

PRICENTRIC BRIEF:

- The Korean government inked a contract with AstraZeneca to purchase 20 million doses, according to the Minister of Health and Welfare Park Neung-hoo, which can inoculate 10 million people, since two injections are required per person
- Another batch is to be purchased from Pfizer, as well as Moderna, in the amount of 20 million doses each—These vaccine candidates are also administered in two injections
- An additional batch, promised through COVID-19 Vaccines Global Access Facility (COVAX), will suffice to inoculate 10 million people, and the government also plans to obtain 4 million doses from Johnson & Johnson's Janssen, which requires just one shot

Health Canada Follows UK in Authorizing Pfizer Vaccine

Date: December 10, 2020 | Country: CANADA-ONTARIO | Region: NORTH AMERICA | Type: Drug Approval | Keywords: #approval #biontech #canada

PRICENTRIC BRIEF:

- Following a review of the evidence, Health Canada has determined that Pfizer and BioNTech's COVID-19 vaccine meets the Department's stringent safety, efficacy and quality requirements for use in Canada, and as such has approved the vaccination
- In the name of transparency and in a bid to gain public trust, Health Canada is also publishing a number of documents related to this decision, including a high-level summary of the evidence that Health Canada reviewed to support the authorization of the vaccine
- The shot received its first approval at the beginning of December, when the UK's Medicines & Healthcare Products Regulatory Agency (MHRA) became the first regulatory body in the world to grant approval to a COVID-19 vaccine, following its Emergency Use Authorization for the Pfizer candidate

FDA Advisory Panel Backs Emergency Use Authorization for Pfizer, BioNTech's BNT162b2

Date: December 11, 2020 | Region: NORTH AMERICA | Type: Drug Approval | Keywords: #advisorypanel #biontech #bnt162b2

PRICENTRIC BRIEF:

- The U.S. Food and Drug Administration (FDA) Vaccine and Related Biological Products Advisory Committee (VRBPAC) has voted 17 to 4 in favor of the FDA granting Emergency Use Authorization (EUA) for Pfizer and BioNTech's COVID-19 vaccine candidate, BNT162b2
- VRBPAC's recommendation was based on data from a pivotal Phase 3 clinical study in which BNT162b2 demonstrated a vaccine efficacy rate

of 95% in patients without prior SARS-CoV-2 infection and also in patients with and without SARS-CoV-2 infection

- The FDA will consider its Committee's recommendation – although it's non-binding – when deciding on whether to grant EUA for the vaccine

UAE Registers Sinopharm COVID-19 Vaccine, Says Vaccine 86% Effective

Date: December 11, 2020 | Country: UNITED ARAB EMIRATES | Region: MIDDLE EAST | Type: Regulation | Keywords: #eua #mohap #sinopharm #vaccine

PRICENTRIC BRIEF:

- The UAE Ministry of Health and Prevention (MOHAP) has announced the registration of Beijing Institute of Biological Product's COVID-19 vaccine, following the review of an application submitted by Sinopharm CNB
- As reported by the UAE's official state media Emirate News Agency, MOHAP and the Department of Health Abu Dhabi reviewed Sinopharm CNBG's interim analysis from Phase 2 clinical trials, finding Beijing Institute of Biological Product's vaccine to have an 86% efficacy against COVID-19 infection
- In September, MOHAP granted the vaccine Emergency Use Authorization (EUA) to allow frontline workers access and has noted similar safety and efficacy profiles for the vaccine as the interim analysis through its Post Authorization Safety Study (PASS) and a Post Authorization Efficacy Study (PAES)

FDA Advisory Panel Backs Emergency Use Authorization for Pfizer, BioNTech's BNT162b2

Date: December 11, 2020 | Region: NORTH AMERICA | Type: Drug Approval | Keywords: #advisorypanel #biontech #bnt162b2 #covid19

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- VRBPAC's recommendation was based on data from a pivotal Phase 3 clinical study in which BNT162b2 demonstrated a vaccine efficacy rate of 95% in patients without prior SARS-CoV-2 infection and also in patients with and without SARS-CoV-2 infection
- The FDA will consider its Committee's recommendation – although it's non-binding – when deciding on whether to grant EUA for the vaccine

FDA Issues EUA for Pfizer's COVID-19 Vaccine

Date: December 14, 2020 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Regulation | Keywords: #covid-19 #eua #fda #pfizer

PRICENTRIC BRIEF:

- The U.S. Food and Drug Administration issued its first emergency use authorization (EUA) for a COVID-19 vaccine, moving the U.S. one step closer to getting the spread of the pandemic under control
- The EUA allows the candidate, Pfizer-BioNTech's BNT162b2 vaccine, to be distributed in the U.S. following "clear evidence that [the vaccine] may be effective in preventing COVID-19"
- Pfizer has a deal with the U.S. government to supply 100 million doses of the vaccine by next March

Moderna Agrees to Supply Singapore with COVID-19 Vaccine

Date: December 15, 2020 | Region: ASIA & SOUTH PACIFIC | Type: Regulation | Keywords: #astrazeneca #covid-19 #eua #moderna #pfizer

PRICENTRIC BRIEF:

- Moderna has announced the signing of an agreement with the Ministry of Health of Singapore to supply its COVID-19 vaccine candidate, mRNA-1273
- Moderna recently announced that the primary efficacy analysis of the Phase 3 COVE study of

the vaccine conducted on 196 cases indicates a vaccine efficacy of 94.1%, and as such has requested Emergency Use Authorization (EUA) from the United States Food and Drug Administration (FDA) and conditional approval from the European Medicines Agency (EMA)

- Moderna currently has purchase agreements in place with other countries including Israel, Belgium, Canada, Korea and the United Kingdom

Bahrain Approves Sinopharm's COVID-19 Vaccine Following UAE

Date: December 15, 2020 | Country: BAHRAIN | Region: MIDDLE EAST | Type: Drug Approval | Keywords: #covid19 #emergencyuseauthorization #eua #nhra #sinopharm #vaccine

PRICENTRIC BRIEF:

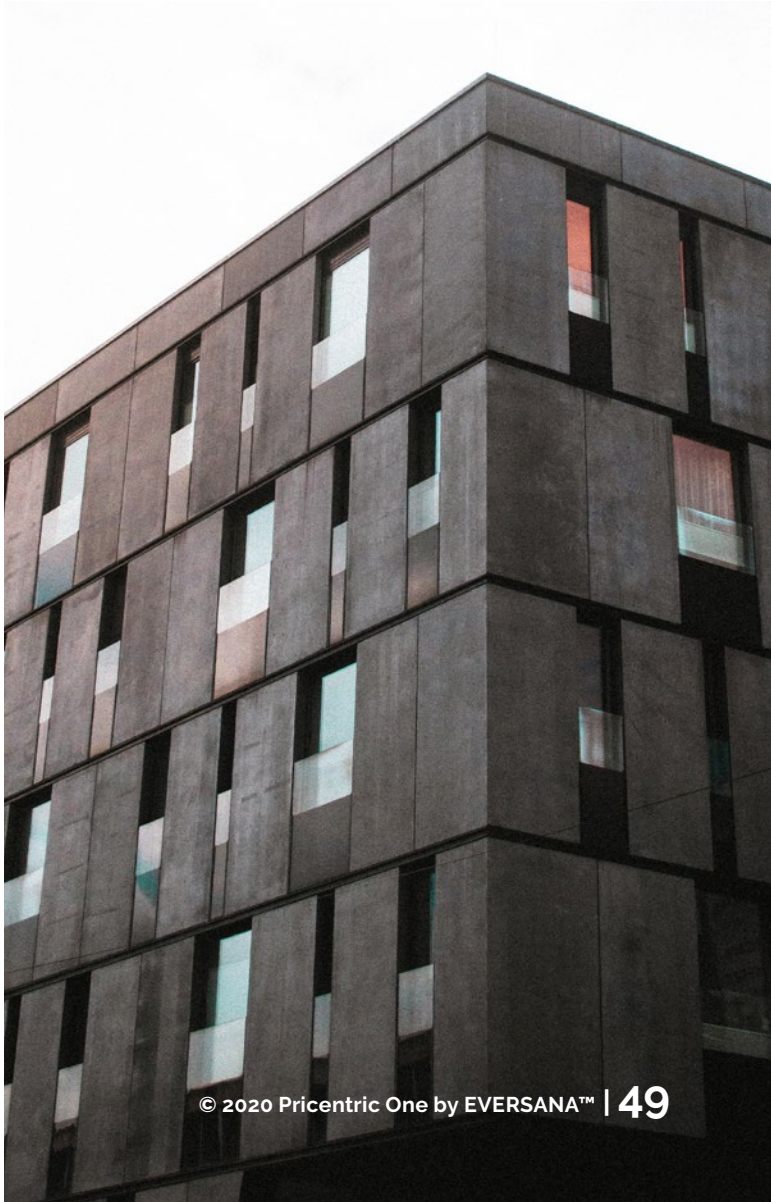
- The National Health Regulatory Authority (NHRA) of Bahrain has approved the registration of Sinopharm's COVID-19 vaccine by G42 Healthcare, Sinopharm's exclusive Middle East and North Africa distributor
- NHRA's backing of the vaccine is based on Phase 3 clinical trial results showing Sinopharm's vaccine had an 86% efficacy rate, 99% seroconversion rate of neutralizing antibody, and 100% effectiveness in preventing moderate to severe COVID-19 cases
- Last week, Bahrain's neighbor the United Arab Emirates (UAE) announced the registration of the vaccine, following a review of the application submitted by Sinopharm

BioNTech, Fosun to Supply 100 M COVID-19 Vaccine Doses to China

Date: December 16, 2020 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: Regulation | Keywords: #biontech #bnt162b2 #covid19 #fosun #supplyagreement #vaccine

PRICENTRIC BRIEF:

- German-based BioNTech and Shanghai Fosun Pharmaceutical have agreed to supply Mainland China with an initial 100 million doses of their COVID-19 vaccine candidate BNT162b2
- In November of this year, the companies kicked off a Phase 2 clinical trial of BNT162b2 in China's Jiangsu Province, the data from which is to be used to support a Biologic License Application (BLA)
- Wu Yifang, Chairperson and CEO of Fosun Pharma, commented, "With the support of the Joint Prevention and Control Mechanism of the State Council, especially the National Medical Products Administration, the National Health Commission, the Ministry of Science and Technology and other relevant authorities, the R&D and clinical trial of our COVID-19 mRNA vaccine in China has been moved forward rapidly"
- Moderna has announced the signing of an agreement with the Ministry of Health of Singapore to supply its COVID-19 vaccine candidate, mRNA-1273
- Moderna recently announced that the primary efficacy analysis of the Phase 3 COVE study of the vaccine conducted on 196 cases indicates a vaccine efficacy of 94.1%, and as such has requested Emergency Use Authorization (EUA) from the United States Food and Drug



FDA Endorses Moderna COVID-19 Vaccine, Suggesting EUA Could be Near

Date: December 16, 2020 | Region: NORTH AMERICA | Type: Regulation | Keywords: #covid #efficacy #euav #fda #moderna #vaccine

PRICENTRIC BRIEF:

- The U.S. Food and Drug Administration (FDA) has found Moderna's COVID-19 vaccine candidate to be safe and "highly effective," indicating that the drug could soon be authorized for use in the U.S.
- The report confirmed the shot's efficacy, reading: "The two-dose vaccination regimen was highly effective in preventing PCR-confirmed Covid-19 occurring at least 14 days after receipt of the second dose"
- Moderna signed a pre-purchase agreement with the U.S. in August, in a deal that awarded the company up to $1.525 billion for the manufacturing and delivery of the doses, including incentive payments for timely delivery of the product

Europe Wraps Exploratory Talks with Novavax for 7th COVID-19 Vaccine

Date: December 17, 2020 | Country: BELGIUM | Region: EU28, EUROPE | Type: Regulation | Keywords: #access #advancedpurchaseagreement #covid19 #europeancomission #novavax

PRICENTRIC BRIEF:

- The European Commission has wrapped exploratory talks with Novavax regarding the purchase of 100 million doses of COVID-19 vaccine candidate NVX-CoV2373, with the option for an additional 100 million doses
- Already the Commission has signed contracts with AstraZeneca (AZ), Sanofi-GlaxoSmithKline (GSK), Janssen, BioNTech and Pfizer, CureVac, and Moderna
- Stella Kyriakides, Commissioner for Health and Food Safety, commented, "All Member States must now ensure that they are ready to start deploying [the vaccines] as from early 2021 once proven to be safe and effective"

New Zealand, Novavax Agree to 10.7 M Doses of Company's COVID-19 Vaccine Candidate

Date: December 17, 2020 | Country: NEW ZEALAND | Region: ASIA & SOUTH PACIFIC | Type: Regulation | Keywords: #advancedpurchaseagreement #covid19 #medsafe #novavax #nvx-cov2373

PRICENTRIC BRIEF:

- Novavax has inked an Advanced Purchase Agreement with the Government of New Zealand for the purchase of 10.7 million doses of the company's COVID-19 vaccine candidate, NVX-CoV2373
- The agreement stipulates that Novavax will manufacture the vaccine with the goal of delivering initial doses by mid-2021 and Novavax will work with New Zealand's health regulator Medsafe to obtain approval
- At this time, NVX-CoV2373 is currently in Phase 3 clinical testing in the United Kingdom

Rosstat to Monitor COVID-19 Treatment Prices in 2021

Date: December 18, 2020 | Country: RUSSIA | Region: ASIA & SOUTH PACIFIC, EUROPE | Type: Regulation | Keywords: #covid19 #pricemonitoring #rosstat #vaccines #vitalandessentialdrugs

PRICENTRIC BRIEF:

- Russia's Federal State Statistics Service (Rosstat) will start monitoring the prices of medicines intended to treat COVID-19 patients in 2021, specifically prices for azithromycin, ceftriaxone, oseltamivir, apixaban, and vitamin D3
- Already Rosstat monitors the prices of 43 medicines on a monthly basis—of these 43 medicines, 19 are listed in the Vital and Essential Drugs List (VED)
- At the end of November, Russia Prime Minister Mikhail Mishustin announced that 25 new medicines, including four drugs covered by the high-cost nosologies program (VZN), and all vaccines against SARS-CoV-2 will be included in the VED starting from next year

Chile Authorizes Emergency Use of Pfizer, BioNTech's BNT162b2

Date: December 18, 2020 | Country: CHILE | Region: SOUTH AMERICA | Type: Drug Approval | Keywords: #biontech #bnt162b2 #chileanpublichealthinstitute #covid19

PRICENTRIC BRIEF:

- The Chilean Public Health Institute (ISP) and an expert committee have authorized emergency use of Pfizer and BioNTech's COVID-19 vaccine BNT162b2 after a unanimous vote in favor
- ISP Director Heriberto García commented, "We have just given the go-ahead to approve the Pfizer BioNTech vaccine in Chile, after an arduous analysis that started on November 27, the day that Pfizer's information arrived in Chile," after adding that Chile is prepared to distribute BNT162b2
- While Pfizer and BioNTech's vaccine has been granted emergency use authorization (EUA), Chile has granted approval for clinical trials for Janssen's, AstraZeneca's, Sinovac's and CanSino's vaccine candidates to be conducted in Chile

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	over 90%	$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	encouraging response	~ $10 [3]	$1 billion
Gamaleya Research Institute	Gam-Covid-Vac (Sputnik V)	viral vector	3	92%	-	-
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	modest response	$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 published a technology assessment report on **Biomarin's Palynziq (pegvaliase)** for treatment of patients aged 16 years or over suffering from phenylketonuria and having uncontrolled hyperphenylalaninemia (blood phenylalanine levels greater than 600 µmol / L) despite being supported by the available treatment options. The actual benefit of Palynziq is moderate for the indication in the Marketing Authorization. The Committee considers that Palynziq provides a minor improvement in actual benefit ASMR IV in the management strategy for patients aged 16 years or over with phenylketonuria with uncontrolled hyperphenylalaninemia (blood levels of phenylalanine greater than 600 µmol / L) despite being supported by the available treatment options.
- HAS published a technology assessment report on **Biomarin's Palynziq (pegvaliase)** for treatment of patients aged 16 years or over suffering from phenylketonuria and having uncontrolled hyperphenylalaninemia (blood phenylalanine levels greater than 600 µmol / L) despite being supported by the available treatment options. The actual benefit of Palynziq is moderate for the indication in the Marketing Authorization. The Committee considers that Palynziq provides a minor improvement in actual benefit ASMR IV in the management strategy for patients aged 16 years or over with phenylketonuria with uncontrolled hyperphenylalaninemia (blood levels of phenylalanine greater than 600 µmol / L) despite being supported by the available treatment options.
- HAS published a technology assessment report on **Roche's Mabthera (rituximab)** for induction of remission in combination with glucocorticoids in pediatric patients (aged ≥ 2 to <18 years) with granulomatosis with polyangiitis (GPA, Wegener's disease) and microscopic polyangiitis, severe and active. The actual benefit of Mabthera is important in extending the indication of the Marketing Authorization in children aged 2 to less than 18 years. The Committee considers that Mabthera, in combination with glucocorticoids, as in adults, provides a minor improvement in actual benefit ASMR IV in the therapeutic strategy for inducing remission in pediatric patients with GPA and PAM severe and active.
- HAS published a technology assessment report on Swedish orphan **Biovitrum's Kineret (anakinra)** for treatment of patients with familial Mediterranean fever only in the event of resistance, intolerance, or contraindication to colchicine. The actual benefit of Kineret is important in the treatment of patients with FMF who have resistance, intolerance, or a contraindication to colchicine. Kineret does not provide an Improvement in Actual Benefit ASMR V in the management strategy for FMF in patients who are resistant, intolerant, or have a contraindication to colchicine.
- HAS published a technology assessment report on **Novartis' Ilaris (canakinumab)** for treatment of adult still's a disease in patients who have had an inadequate response to previous treatment with non-steroidal anti-inflammatory drugs and systemic corticosteroids. The actual benefit of Ilaris is significant in the new indication in the Marketing Authorization. Ilaris does not provide an Improvement in actual benefit ASMR V in the management strategy for Still's disease.
- HAS published a technology assessment report on **Boehringer Ingelheim's Jardiance (empagliflozin)** for treatment of adults with type 2 diabetes. The actual benefit of Jardiance is important in the treatment of adults with type 2 diabetes which is insufficiently controlled by monotherapy with metformin or a sulphonylurea, in addition to diet and exercise, and only in combination : in dual therapy only with metformin or with a sulphonylurea, as triple therapy only with metformin and a sulphonylurea or with metformin and insulin. Jardiance provides minor improvement in actual benefit ASMR IV.
- HAS published a technology assessment report on **AstraZeneca's Xigduo (dapagliflozin/metformin)** for management of type 2 diabetes. The actual benefit of Xigduo is substantial: in patients insufficiently controlled by metformin alone at the maximum tolerated dose, in patients insufficiently controlled at the maximum dose of metformin combined with a sulfonylurea or insulin, in patients already treated with the combination of dapagliflozin and metformin administered as separate tablets. Xigduo provides a minor improvement in actual benefit ASMR IV.

HTA Decisions: France (cont.)

- HAS published a technology assessment report on **AstraZeneca's Forxiga (dapagliflozin)** for treatment of adults with type 2 diabetes insufficiently controlled by monotherapy with metformin or a sulphonylurea. The actual benefit of Forxiga is important in the treatment of adults with type 2 diabetes which is insufficiently controlled by monotherapy with metformin or a sulphonylurea, as an adjunct to diet and exercise, and only by association: in dual therapy only with metformin or with a sulphonylurea, as triple therapy only with metformin and a sulphonylurea or with metformin and insulin. Forxiga provides a minor improvement in actual benefit ASMR IV.

- HAS published a technology assessment report on **Janssen's Invokana (canagliflozin)** for treatment of adults with type 2 diabetes insufficiently controlled by monotherapy with metformin or a sulphonylurea. The actual benefit of Invokana is substantial in: the treatment of adult patients with type 2 diabetes with stage 2 and stage 3 chronic kidney disease and albuminuria in combination with standard therapy, including a converting enzyme inhibitor or an ACE receptor antagonist angiotensin 2 (ARA II); the treatment of adults with type 2 diabetes which is insufficiently controlled with metformin monotherapy or a sulphonylurea, in addition to diet and exercise, and only in combination: in dual therapy only with metformin or with a sulphonylurea, as triple therapy only with metformin and a sulphonylurea or with metformin and insulin. Invokana provides moderate improvement in actual benefit ASMR III.

- HAS published a technology assessment report on **Janssen's Invokana (canagliflozin)** for treatment of adults with type 2 diabetes insufficiently controlled by monotherapy with metformin or a sulphonylurea. The actual benefit of Invokana is substantial in: the treatment of adult patients with type 2 diabetes with stage 2 and stage 3 chronic kidney disease and albuminuria in combination with standard therapy, including a converting enzyme inhibitor or an ACE receptor antagonist angiotensin 2 (ARA II); the treatment of adults with type 2 diabetes which is insufficiently controlled with metformin monotherapy or a sulphonylurea, in addition to diet and exercise, and only in combination: in dual therapy only with metformin or with a sulphonylurea, as triple therapy only with metformin and a sulphonylurea or with metformin and insulin. Invokana provides minor improvement in actual benefit ASMR IV.

- HAS published a technology assessment report on **Gilead's Sovaldi (sofosbuvir)** for treatment of chronic hepatitis C in pediatric patients aged 3 to less than 12 years. The actual benefit of Sovaldi is substantial in the indication of the Marketing Authorization. The Committee considers that Sovaldi, in combination with ribavirin, does not improve the actual benefit ASMR V in the management of chronic hepatitis C in children aged 3 years to less than 12 years.

- HAS published a technology assessment report on **Gilead's Harvoni (ledipasvir/sofosbuvir)** for treatment of chronic hepatitis C in pediatric patients aged 3 to less than 12 years. The actual benefit of Harvoni is substantial in the indication of the Marketing Authorization. The Committee considers that Harvoni in combination with ribavirin does not improve the actual benefit ASMR V in the management of chronic hepatitis C in children aged 3 years under 12 years old.

- HAS published a technology assessment report on **Novartis' Eucreas (vildagliptin/metformin hydrochloride)** for the treatment of type 2 diabetes. The actual benefit of Eucreas is important in the treatment of adult patients whose glycemic control is insufficient at their maximum tolerated dose of metformin oral monotherapy, or in patients already treated with the combination of vildagliptin and metformin in tablet form. separated as well as in combination with a sulfonylurea (ie triple therapy) as an adjunct to diet and exercise in adult patients insufficiently controlled with metformin and a sulfonylurea. This specialty is a complement to the range which does not improve the actual benefit ASMR V.

- HAS published a technology assessment report on **Novartis' Eucreas (vildagliptin/metformin hydrochloride)** for the treatment of type 2 diabetes. The actual benefit of Eucreas is moderate in triple therapy with insulin as an adjunct to diet and exercise to improve glycemic control in adult patients when insulin at a stable dose and metformin alone do not allow sufficient glycemic control. This specialty is a complement to the range which does not improve the actual benefit ASMR V.

HTA Decisions: France (cont.)

- HAS published a technology assessment report on **Fresenius Kabi's Smoflipid (fat emulsions)** as part of parenteral nutrition. The actual benefit of Smoflipid 200 mg/ml (refined soybean oil, medium-chain triglycerides, refined olive oil, fish oil rich in omega-3 acids), emulsion for infusion is important in the indication of AMM. This is a complement to the range which does not improve the actual benefit ASMR V compared to the already registered presentations of Smoflipid 200 mg/ml.

HTA Decisions: Germany

- G-BA in Germany has published the benefit assessment report on **Kyowa Kirin's Poteligeo (mogamulizumab)** for treatment of adult patients with mycosis fungoides or Sézary syndrome who have received at least one prior systemic therapy. The committee noted that overall, there is a hint of a non-quantifiable added benefit of mogamulizumab compared to vorinostat determined because the scientific data is a quantification does not allow
- G-BA in Germany has published the benefit assessment report on **Kyowa Kirin's Poteligeo (mogamulizumab)** for treatment of adult patients with mycosis fungoides or Sézary syndrome who have received at least one prior systemic therapy. The committee noted that overall, there is a hint of a non-quantifiable added benefit of mogamulizumab compared to vorinostat determined because the scientific data is a quantification does not allow.
- G-BA in Germany has published the benefit assessment report on **Takeda's Adcetris (brentuximab vedotin)** in combination with cyclophosphamide, doxorubicin, and prednisone adult patients with previously untreated systemic anaplastic large cell lymphoma. The committee noted that a hint of a minor added benefit of brentuximab vedotin in combination with CHP versus CHOP in treating adult patients with previously untreated systemic anaplastic large cell lymphoma.

HTA Decisions: Canada

- The CADTH Canadian Drug Expert Committee assessed **Seattle Genetics' Adcetris (brentuximab vedotin)** for treatment of previously untreated patients with stage IV Hodgkin lymphoma in combination with doxorubicin, vinblastine, and dacarbazine. pERC conditionally recommends reimbursement Adcetris if the following condition is met i.e. cost-effectiveness being improved to an acceptable level.
- The CADTH Canadian Drug Expert Committee assessed **Seattle Genetics' Adcetris (brentuximab vedotin)** for treatment of adult patients with primary cutaneous anaplastic large cell lymphoma or cluster of differentiation (CD)30- expressing mycosis fungoides (MF) who have had prior systemic therapy. pERC conditionally recommends the reimbursement of Tecentriq if the following condition is met i.e. cost-effectiveness being improved to an acceptable level.

HTA Decisions: United Kingdom

- NICE has published a technical assessment report on **AbbVie's Venclyxto (venetoclax)** for the treatment of adult patients with previously untreated chronic lymphocytic leukemia. NICE has recommended as an option only if there is a 17p deletion or TP53 mutation, or there is no 17p deletion or TP53 mutation, and fludarabine plus cyclophosphamide and rituximab, or bendamustine plus rituximab, is unsuitable, and the companies provide the drugs according to the commercial arrangements.
- NICE has published a technical assessment report on **Novo Nordisk's Saxenda (liraglutide)** for managing overweight and obesity. NICE has recommended as an option for managing overweight and obesity only if a body mass index (BMI) of at least 35 kg/m2 (or at least 32.5 kg/m2 for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population) and it is prescribed in secondary care by a specialist multidisciplinary tier 3 weight management service and the company provides it according to the commercial arrangement.
- NICE has published a technical assessment report on **AbbVie's Rinvoq (upadacitinib)** for the treatment of moderate to severely active rheumatoid arthritis. NICE has recommended Rinvoq as an option only if the disease is severe (a disease activity score [DAS28] of more than 5.1) and the company provides upadacitinib according to the commercial arrangement.
- NICE has published a technical assessment report on **Roche's Tecentriq (atezolizumab)** for treatment of adult patients with advanced or unresectable hepatocellular carcinoma who have not received prior systemic therapy. Atezolizumab plus bevacizumab is recommended as an option only if they have Child-Pugh grade A liver impairment and an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 and the company provides it according to the commercial arrangement.
- NICE has published a technical assessment report on **Sanofi's Cablivi (caplacizumab)** for treating adults and young people aged 12 years and over who weigh at least 40 kg who are 'experiencing an episode of acquired thrombotic thrombocytopenic purpura, in conjunction with plasma exchange and immunosuppression'. The committee noted that Cablivi with plasma exchange and immunosuppression is recommended, within its marketing authorization, as an option only if the company provides caplacizumab according to the commercial arrangement.

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Drug Approvals: United States

- **HETLIOZ (TASIMELTEON)** was approved by the FDA in Non-24-Hour Sleep-Wake Disorder (Non-24) in adults; and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
  COMPANY: VANDA PHARMS INC
- **HETLIOZ LQ (TASIMELTEON)** was approved by the FDA in Non-24-Hour Sleep-Wake Disorder (Non-24) in adults; and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
  COMPANY: VANDA PHARMS INC
- **GALLIUM Ga 68 PSMA-11 (PSMA-11 GA 68)** was approved by the FDA for positron emission tomography (PET) of prostatespecific membrane antigen (PSMA) positive lesions in men with prostate cancer
  COMPANY: UNIV CA LOS ANGELES
- **GAVRETO (PRALSETINIB)** was approved for THYROID CANCER by the FDA in metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer; advanced or metastatic RET-mutant medullary thyroid cancer (MTC); and advanced or metastatic RET fusion-positive thyroid cancer
  COMPANY: BLUEPRINT MEDICINES
- **ORLADEYO (BEROTRALSTAT)** was approved by the FDA for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older
  COMPANY: BIOCRYST
- **SAXENDA (LIRAGLUTIDE)** was approved by the FDA to treat obesity in adults and adolescents
  COMPANY: Novo Nordisk
- **KLISYRI (TIRBANIBULIN)** was approved by the FDA for the topical treatment of actinic keratosis of the face or scalp
  COMPANY: ATHENEX
- **MARGENZA (MARGETUXIMAB-CMKB)** was approved by the FDA for the treatment of adult patients with metastatic HER2-positive breast cancer
  COMPANY: MACROGENICS

Drug Approvals: China

- **BLINCYTO (BLINATUMOMAB)** was approved by the NMPA for the treatment of adult patients with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL)
  COMPANY: BEIGENE
- **TAKHZYRO (LANADELUMAB)** was approved by the NMPA for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older
  COMPANY: TAKEDA

Drug Approvals: EMA

- **RINVOQ (UPADACITINIB)** was approved by the EMA in Psoriatic arthritis and Ankylosing spondylitis
  COMPANY: ABBVIE
- **BAVENCIO (AVELUMAB)** was approved by the EMA as monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC)
  COMPANY: MERCK
- **INREBIC (FEDRATINIB)** was approved by the EMA for the treatment of primary myelofibrosis and of myelofibrosis secondary to polycythaemia vera or essential thrombocythaemia
  COMPANY: CELGENE
- **KIXELLE (INSULIN ASPART)** was approved by the EMA for the treatment of diabetes mellitus
  COMPANY: MYLAN
- **LENALIDOMIDE KRKA (LENALIDOMIDE)** was approved by the EMA for the treatment of multiple myeloma and follicular lymphoma
  COMPANY: KRKA, d.d., NOVO MESTO
- **LENALIDOMIDE KRKA D.D. (LENALIDOMIDE)** was approved by the EMA for the treatment of multiple myeloma, myelodysplastic syndromes, and follicular lymphoma
  COMPANY: KRKA, d.d., NOVO MESTO
- **LENALIDOMIDE KRKA D.D. NOVO MESTO (LENALIDOMIDE)** was approved by the EMA for the treatment of multiple myeloma, myelodysplastic syndromes, mantle cell lymphoma and follicular lymphoma
  COMPANY: KRKA, d.d., NOVO MESTO
- **LUMOXITI (MOXETUMOMAB PASUDOTOX)** was approved by the EMA for the treatment of relapsed or refractory hairy cell leukaemia.
  COMPANY:ASTRAZENECA
- **OGLUO (GLUCAGON)** was approved by the EMA for the treatment of severe hypoglycaemia in diabetes mellitus
  COMPANY: XERIS
- **RETSEVMO (SELPERCATINIB)** was approved by the EMA for the treatment of cancers that display rearranged during transfection (RET) gene alterations
  COMPANY:ELI LILLY
- **RUKOBIA (FOSTEMSAVIR)** was approved by the EMA for the treatment of multidrug resistant HIV-1 infection
  COMPANY: ViiV HEALTHCARE
- **SIBNAYAL (POTASSIUM CITRATE AND POTASSIUM HYDROGEN CARBONATE)** was approved by the EMA for the treatment of distal renal tubular acidosis
  COMPANY: ADVICENNE
- **SUNITINIB ACCORD (SUNITINIB)** was approved by the EMA in tumour growth, pathologic angiogenesis, and metastatic progression of cancer
  COMPANY: ACCORD HEALTHCARE

Drug Approvals: EMA

- **YUFLYMA (ADALIMUMAB)** was approved by the EMA for the treatment of certain inflammatory and autoimmune disorders
COMPANY: CELLTRION HEALTHCARE

- **TUKYSA (TUCATINIB)** was approved by the EMA for the treatment of HER2-positive locally advanced or metastatic breast cancer
COMPANY: SEAGEN

- **KEYTRUDA (PEMBROLIZUMAB)** was approved by the EMA for the firstline treatment of metastatic microsatellite instabilityhigh (MSIH) or mismatch repair deficient (dMMR) colorectal cancer in adults
COMPANY: MERCK SHARP & DOHME

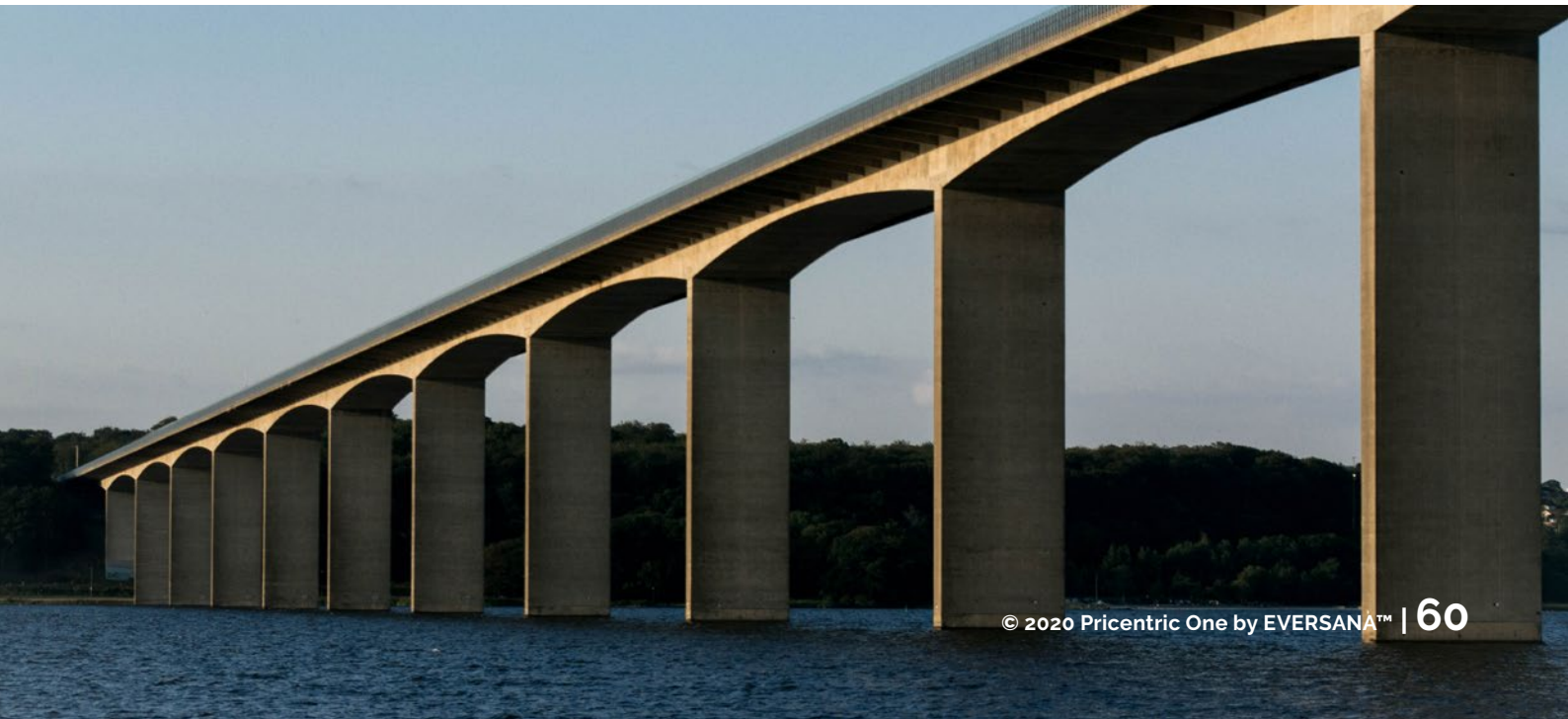
- **BAVENCIO (AVELUMAB)** was approved by the EMA in adult patients with locally advanced or metastatic urothelial carcinoma (UC)
COMPANY: MERCK

- **RINVOQ (UPADACITINIB)** was approved by the EMA active psoriatic arthritis and active ankylosing spondylitis in adult patients
COMPANY: ABBVIE

- **TRIXEO AEROSPHERE (FORMOTEROL, GLYCOPYRRONIUM BROMIDE AND BUDESONIDE)** was approved by the EMA in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD)
COMPANY: ASTRAZENECA

Drug Approvals: Canada

- **ZOLGENSMA (ONASEMNOGENE ABEPARVOVEC)** was approved by the HEALTH CANADA for the treatment of pediatric patients with 5q spinal muscular atrophy (SMA)
COMPANY: NOVARTIS



Germany: Post-AMNOG Price Changes for Originator Drugs

Company	Product Group	Generic Name	Description	MNF (Euro)	OLD MNF	Change	%Change
MERCK	MAVENCLAD	CLADRIBINE	MAVENCLAD TAB 1 PACK 1 TABS 10 MG	1615.00	1636.25	-21.25	-1.30%
MERCK	MAVENCLAD	CLADRIBINE	MAVENCLAD TAB 1 PACK 4 TABS 10 MG	6460.00	6545.00	-85.00	-1.30%
MERCK	MAVENCLAD	CLADRIBINE	MAVENCLAD TAB 1 PACK 6 TABS 10 MG	9690.00	9817.50	-127.50	-1.30%
ROCHE	TECENTRIQ	ATEZOLIZUMAB	TECENTRIQ INF 1 VIAL 14 ML 840 MG	2329.07	2646.87	-317.80	-12.01%
ROCHE	TECENTRIQ	ATEZOLIZUMAB	TECENTRIQ INF 1 VIAL 20 ML 1200 MG	3327.24	3781.25	-454.01	-12.01%
BAYER	VITRAKVI	LAROTRECTINIB	VITRAKVI CAP 1 PACK 56 CAPS 100 MG	4375.17	15000.00	-10624.83	-70.83%
BAYER	VITRAKVI	LAROTRECTINIB	VITRAKVI CAP 1 PACK 56 CAPS 25 MG	1093.79	5000.00	-3906.21	-78.12%
BAYER	VITRAKVI	LAROTRECTINIB	VITRAKVI ORAL SOL 1 BOTT 100 ML 2000 MG	1562.56	5357.14	-3794.58	-70.83%

Drug Launches: Europe & US

Country	Generic Name	Product Group	Company	Indication	Approval Date	Launch Date
GERMANY	CRIZANLIZUMAB	ADAKVEO	NOVARTIS	VASO-OCCLUSIVE CRISIS	28/10/2020	01/12/2020
GERMANY	ACALABRUTINIB	CALQUENCE	ASTRAZENECA	CLL	05/11/2020	01/12/2020
ITALY	MOGAMULIZUMAB	POTELIGEO	KYOWA KIRIN	SEZARY SYNDROME	22/11/2018	11/12/2020
ITALY	UPADACITINIB	RINVOQ	ABBVIE	RHEUMATOID ARTHRITIS	16/12/2019	10/12/2020
ITALY	TRASTUZUMAB	ZERCEPAC	ACCORD	BREAST CANCER	27/07/2020	11/12/2020
SPAIN	UPADACITINIB	RINVOQ	ABBVIE	RHEUMATOID ARTHRITIS	16/12/2019	01/12/2020
UNITED STATES	LUMASIRAN	OXLUMO	ALNYLAM	PRIMARY HYPEROXALURIA TYPE 1	19/11/2020	01/12/2020

Price Changes: Europe & US

Country	Generic Name	Product Group	Company	Therapeutic Area	Avg. Price Change all SKU	First Pricing Date
FRANCE	APALUTAMIDE	ERLEADA	JANSSEN	ONCOLOGY	-21.40%	01/04/2020
FRANCE	BEVACIZUMAB	AYBINTIO	MERCK	ONCOLOGY	-30.00%	30/10/2020
GERMANY	ATEZOLIZUMAB	TECENTRIQ	ROCHE	ONCOLOGY	-12.01%	15/10/2017
GERMANY	CLADRIBINE	MAVENCLAD	MERCK	ONCOLOGY	-1.30%	15/09/2017
GERMANY	GILTERITINIB	XOSPATA	ASTELLAS	ONCOLOGY	-15.20%	01/12/2019
GERMANY	PEGFILGRASTIM	PELGRAZ	ACCORD	HEMATOLOGY	-27.92%	15/10/2018
GERMANY	PIRITRAMIDE	DIPIDOLOR	PIRAMAL	NEUROLOGY	-10.04%	15/07/2004
UNITED KINGDOM	GUAIFENESIN	ROBITUSSIN	PFIZER	RESPIRATORY	-7.13%	01/10/2009
UNITED STATES	ZOLMITRIPTAN	ZOMIG	AMNEAL	NEUROLOGY	+9.90%	01/04/2005

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