PRICENTRIC ONE
BY EVERSANA™

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Pricentric INSIGHT: Could Waiving Vaccine Patent Rights Help Us Win the Fight Against COVID-19?

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Cell & Gene Collective Launches to Raise Awareness of Promises, Challenges of Cell, Gene Therapy

Astellas, bluebird bio, Bristol-Myers Squibb (BMS), Kite (a Gilead company), and Novartis have launched the Cell & Gene Collective to raise awareness of the promises and challenges of cell and gene therapies.

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Pricentric INSIGHT: Could Waiving Vaccine Patent Rights Help Us Win the Fight Against COVID-19?

PRICENTRIC BRIEF:

- On May 5, the Biden administration supported waiving intellectual property rights for COVID-19 vaccines in a surprise U-turn on its previous stance — the EU promptly followed suit by announcing it would be willing to discuss the idea, and China also recently expressed support for the notion
- South Africa and India initially made the vaccine waiver proposal at the WTO in October last year, at the time gathering support from more than 100 developing and low-middle-income countries that would benefit directly from making vaccines, or the intellectual property behind them, more widely available
- Despite the U.S.' decision gaining support from the likes of WHO and GAVI, there are many nuances that could make the implementation less straight forward that it may first seem — As pharma heavyweights have been quick to explain, removing intellectual property protection does not immediately equal increased production and increased vaccination numbers

THE DETAILS

WASHINGTON D.C., United States & BRUSSELS, Belgium – On May 5, the Biden administration supported waiving intellectual property rights for COVID-19 vaccines in a surprise U-turn on the U.S.' previous stance.

Up until now, the U.S. has been against waiving patents on the vaccines, but under increasing pressure, Biden now appears to have changed his mind.

In a statement, Katherine Tai, the United States trade representative, announced: "This is a global health crisis, and the extraordinary circumstances of the Covid-19 pandemic call for extraordinary measures. The administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for Covid-19 vaccines."

"Those negotiations [with the World Trade Organization] will take time given the consensus-based nature of the institution and the complexity of the issues involved."

Shortly after the statement, European Commission president Ursula von der Leyen announced that the EU could be willing to discuss a similar proposal to waive intellectual property rights for COVID-19 vaccines.

Speaking to the European University Institute in Florence, she noted: "The European Union is ready to discuss any proposal that addresses the crisis in an effective and pragmatic manner. That is why we are ready to discuss how the U.S. proposal for a waiver on intellectual property protection for COVID-19 vaccines could help achieve that objective.

"In the short run, however, we call upon all vaccine producing countries to allow exports and to avoid measures that disrupt supply chains."

Despite the Commission's initial support for the idea, Members of the European Parliament (MEPs) clashed over proposals at a plenary meeting on the topic.
Geert Bourgeois (ECR, Belgium) also called the patent waiver a "false good idea," explaining "Nobody has been able to demonstrate that the waiver of patents will lead to a speed up and increase of vaccines. Vaccine production is highly complex; production and quality control take so many years to set up that waiving patents will have no effect in 2021. The real solution lies is in bringing about a drastic increase in production here and it would appear we are succeeding in doing that."

The group will make a final decision on the matter in June, at the next plenary session.

Most recently, China expressed support for the idea, with Foreign Ministry spokesman Zhao Lijian echoing the U.S. and Europe's sentiments: "China will continue to make a contribution to the fairness and accessibility of vaccines in developing countries. China fully understands and supports the request of developing countries to exempt the intellectual property rights for novel coronavirus vaccines."

GAVI, WHO Welcome Proposals

On the news, the GAVI vaccine alliance welcomed Biden's decision, urging Washington to help manufacturers transfer know-how to boost global production.

In a statement, the organization explained, "We recognize also the significance of the (Biden) administration's commitment to work towards increasing raw material production, which will have an immediate impact on alleviating current global supply constraints."

"GAVI urges now that in the interests of global equitable access, that the US supports manufacturers to transfer not only IP but also know-how in a bid to urgently boost global production."

"GAVI also urges the international community to share doses with COVAX immediately to help those countries that have been worst hit by current global supply constraints and urgently need to protect their most at-risk populations."

The World Health Organization (WHO), a long time supporter of abolishing patents for COVID-19 vaccines, also expressed its support of Biden's move, calling it "a powerful example of American leadership to address global health challenges."

WHO Director-General, Dr Tedros Adhanom Ghebreyesus, added, "I commend the United States on its historic decision for vaccine equity and prioritizing the well-being of all people everywhere at a critical time. Now let's all move together swiftly, in solidarity, building on the ingenuity and commitment of scientists who produced life-saving COVID-19 vaccines."

Initial WTO Proposal

South Africa and India initially made the vaccine waiver proposal at the WTO in October last year, at the time gathering support from more than 100 developing and low-middle-income countries that would benefit directly from making vaccines, or the intellectual property behind them, more widely available.

In a document, the countries explained: "Given this present context of global emergency, it is important for WTO Members to work together to ensure that intellectual property rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19."

WHO welcomed the move, tweeting: "WHO welcomes South Africa's and India's recent proposal to WTO to ease international & intellectual property agreements on #COVID19 vaccines, treatments & tests in order to make the tools available to all who need them at an affordable cost."

However, at the time, the U.S., EU, UK, Switzerland and Brazil blocked India and South Africa's proposal.

While the intention of the waiver is undeniably well intended, there are many nuances that could make the implementation less straight forward that it may first seem. Removing intellectual property protection does not immediately equal increased production and increased vaccination numbers.

"Short-sighted" Move?

In contrast to the support, The European Federation of Pharmaceutical Industries and Associations (EFPIA), believes that if Biden's initiative is actually approved by the WTO, the waiver would remove incentives for companies to continue research into new variants, new diagnostics, treatments and vaccines to tackle the pandemic.

EFPIA Director, General Nathalie Moll, called the move "short-sighted and ineffectual," suggesting that it "puts the hard-won progress in fighting this terrible disease in jeopardy."

She continued, "While we wholeheartedly agree with the goal of protecting citizens around the world through vaccines, waiving patents will make winning the fight against the coronavirus even harder."

"Increasing capacity to deliver doses to citizens around the world requires the skills and technical know-how of the vaccine developer to bring on-board partner manufacturing organizations.

"You simply cannot achieve this kind of capacity expansion by waiving patents and hoping that hitherto unknown factories around the world will turn their hand to the complex process of vaccine manufacture."

She suggested, instead, that focus should be on removing barriers to collaboration, ensuring the free flow of materials around the world and continuing the research effort.

The International Federation of Pharmaceutical Manufacturers & Associations has also taken umbrage with the decision, noting: "Waiving patents of Covid-19 vaccines will not increase production nor provide practical solutions needed to battle this global health crisis."

Patents Support Innovation

The move is also proving unpopular with various pharma lobbyists who stand to lose out from relinquishing their patent rights, as highlighted by The Pharmaceutical Research and Manufacturers of America (PhRMA).

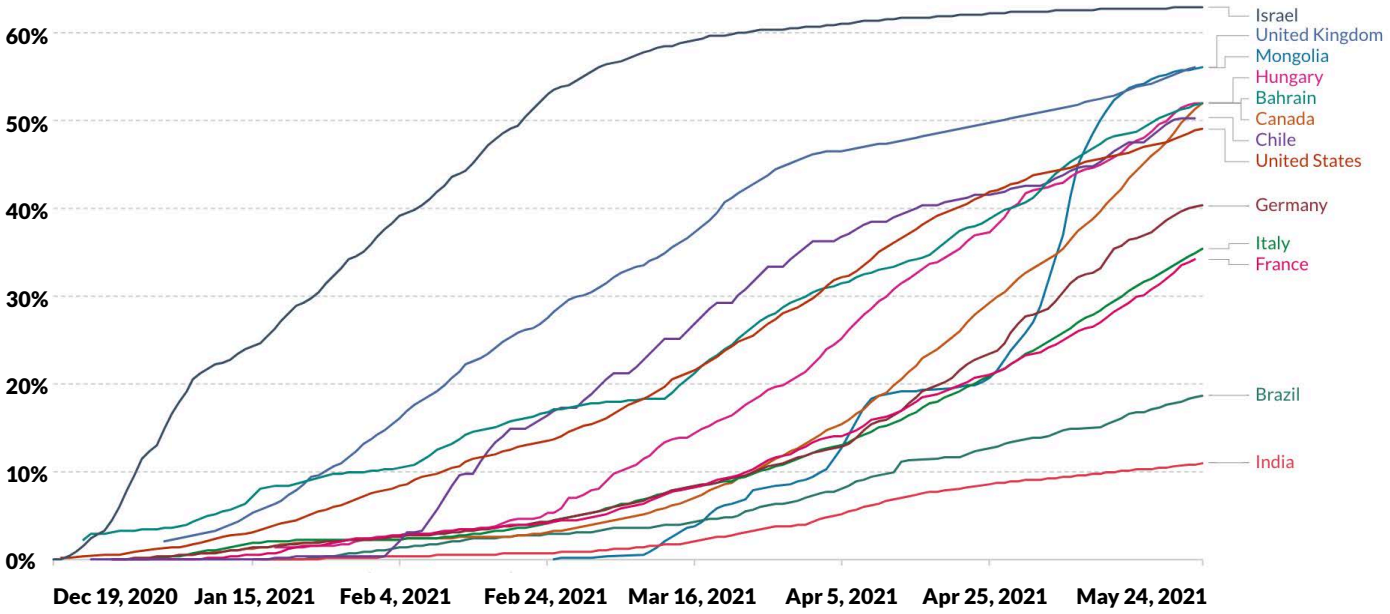
The group's CEO, Stephen J. Ubl, explained that the "unprecedented step" could "undermine our global response to the pandemic and compromise safety."

He added, "This decision will sow confusion between public and private partners, further weaken already strained supply chains and foster the proliferation of counterfeit vaccines."

In addition, Stéphane Bancel, CEO of Moderna – a company utilizing the innovation of messenger RNA (mRNA) for its vaccine - suggested a patent waiver "will not help supply

Share of people who received at least one dose of COVID-19 vaccine

Share of the total population that received at least one vaccine dose.
This may not equal the share that are fully vaccinated if the vaccine requires two doses.



Mathieu, E., Ritchie, H., Ortiz-Ospina, E. et al. (2021). *Coronavirus (COVID-19) Vaccinations*. Our World in Data. https://ourworldindata.org/covid-vaccinations Our World in Data

more mRNA vaccines to the world any faster in 2021 and 2022, which is the most critical time of the pandemic. There is no idle mRNA manufacturing capacity in the world."

The overriding concern from pharma companies is that the waiver sets a precedent for the future, enabling easier suspension of intellectual property rights for innovative drugs in the future, thus removing incentive to invest in research and development. Removing the short-term monopoly that a company receives with new patented technology could ultimately harm the pharmaceutical industry and a number of other indications outside COVID-19, stunting technical progression and investment in future innovation.

All the Idea, No Gear

In addition to potentially harming future innovation, eliminating rights to vaccine patents will not immediately mitigate existing supply issues, primarily due to availability of the needed raw ingredients.

The seemingly counterintuitive – in the circumstance of waiving vaccine patents for other countries – U.S. Defense Production Act gives U.S.-based drug producers priority access to the necessary materials needed to make such specialist vaccines.

As such, drugmakers who would be given access to what is essentially the recipe of the vaccine but would still need to be able to source the ingredients.
Michelle McMurry-Heath, CEO of the Biotechnology Innovation Organization (BIO) explained in a statement: "Handing needy countries a recipe book without the ingredients, safeguards, and sizable workforce needed will not help people waiting for the vaccine."

Even before a patent waiver was in discussion, severe delays have been occurring in particular deliveries of COVID-19 vaccines produced by the Serum Institute of India (SII) to lower-income economies participating in the COVAX Facility.

Consideration needs to be given to temperature stability, transportation, and other logistical issues related to complex supply chain needs. For example, the Moderna jab needs to be stored in refrigerated conditions between 2°C and 8°C (36°F and 46°F) for up to 30 days before the vials are punctured for use. Pfizer's shots require 70C and -80C conditions all the way from the production facility to the patient. AstraZeneca's vaccine can be stored, transported and handled at normal refrigerated conditions (2-8°C/36-46°F) for at least six months and administered within existing healthcare settings, but all three still require a certain standard of refrigeration, which can be difficult for countries with underdeveloped supply chains.

Because of these considerations, in an interview with STAT news, a number of experts suggested that the waiver could be more "symbolic" than substantial, as increased capacity could not feasibly be seen from the move until at least 2022.

Prashant Yadav, supply chain expert and senior fellow at the Center for Global Development believes that "By itself, it will not get us much benefit in increased manufacturing capacity. But as part of a larger package, it can."

Here to Help

EVERSANA uniquely has the people, methods, and tools to assist businesses in navigating any changing pharmaceutical policies, even in such unsure times. This expertise is built on our combined decades of experience solving problems in and building tools for global pricing intelligence, global visibility, and product launch expertise, which puts us in a trusted position to advise clients on how to handle these changes.

At the same time, Pricentric INSIGHTS strives to deliver accurate, comprehensive insights on major policy and regulatory changes, as well as HTA decisions and drug approvals, in over 100+ markets around the world. Our team of researchers checks a database of over 700+ reliable sources, including everything from government databases to local newspapers, to provide readers with in-depth updates on the ever-changing pricing and reimbursement landscape. In addition, we provide conference coverage and utilize our team of consultants to detail how major changes, such as those proposed by Biden, can impact market access and the global pricing landscape.

Pricentric INSIGHT: BeNeLuxA's Push for Innovative Drug Price Reduction Sees Zolgensma, Vertex's CF Portfolio in Firing Line

PRICENTRIC BRIEF

- At the start of May, the Netherlands' Zorginstituut (ZIN) advised the country's Minister for Medical Care to only reimburse Novartis' Zolgensma (onasemnogene abeparvovec) as part of the country's basic package after a substantial price reduction and a potential performance-related payment plan
- The decision is not the first of its kind for ZIN, as it comes shortly after the group advised the Minister of Medical Care to exclude Vertex's triple-combination therapy Kaftrio (elexacaftor/tezacaftor/ivacaftor) plus Kalydeco (ivacaftor) from the Medicines Reimbursement System (GVS) unless the company meets a handful of conditions, including reducing the price of the drug by 75%
- BeNeLuxA's variance in success so far with securing access to expensive, innovative medicines raises the question of whether the initiative represents the future of both market access and pricing and reimbursement negotiations – However, the latest price reduction requests show that the international group is assured that its bargaining power is much stronger collectively than the countries are individually

THE DETAILS

AMSTERDAM, The Netherlands – At the start of May, the Netherlands' Zorginstituut (ZIN) advised the country's Minister for Medical Care to only reimburse Novartis' Zolgensma (onasemnogene abeparvovec) as part of the country's basic package after a substantial price reduction and a potential performance-related payment plan.

The agency outlined two conditions for the therapy's reimbursement:

- The price must be reduced by about 50%
- There must be a pay for performance agreement with the manufacturer

The decision is not the first of its kind for ZIN, as it comes shortly after the group advised the Minister of Medical Care to exclude Vertex's triple-combination therapy Kaftrio (elexacaftor/tezacaftor/ivacaftor) plus Kalydeco (ivacaftor) from the Medicines Reimbursement System (GVS) unless the company meets a handful of conditions, including reducing the price of the drug by 75%.

Zolgensma Price Reduction Request

On May 7, ZIN noted in a statement that Zolgensma "holds great promise," but that "little research has been done and there is no evidence yet that the effect of Zolgensma is permanent."

Sjaak Wijma, chairman of the board explained: "We would like to give Zolgensma the benefit of the doubt, but not at any cost. After all, we reimburse such a means from the premiums we collect together and we want to spend that money on as much good care as possible."

The Advisory Committee Package (ACP) reviewed the AveXis/Novartis gene therapy in its Friday 23 April meeting and deduced that in order to gain more certainty about the long-term effects, a data collecting scheme will be implemented over the coming years via the existing SMA register.

The assessment of the EUR 1.9 million therapy was undertaken by ZIN, but the outcome was determined together with Ireland and Belgium under the BeNeLuxa initiative.

Zolgensma is currently conditionally approved in Europe for the treatment of patients with 5q SMA with a 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.

Following conditional approval for Zolgensma in May 2020, BeNeLuxA announced it wanted to enter discussions with AveXis/Novartis on access and affordability. Belgium, Ireland, and the Netherlands decided to undertake a joint health technology assessment (HTA) of Zolgensma as part of the application by the drugmaker, with Austria acting as an expert reviewer during the procedure.

Since ZIN's assessment, Ireland echoed its sentiments and published its assessment under the same cross-border initiative. The group declared that the comparative benefit of Zolgensma over the comparator, Biogen's Spinraza (nusinersen), is unknown, whereas the gene therapy's benefit over best supportive care is likely to be greater, despite some uncertainties.

Similarly to the Netherlands, the NCPE concluded that Zolgensma not be considered for reimbursement unless cost effectiveness can be improved relative to existing treatments.

Vertex' Cystic Fibrosis Portfolio

While ZIN stated earlier this month that it is confident in the effect of Kaftrio and Kalydeco, especially when it comes to improving lung function and reducing respiratory complaints, the agency is uncertain of the long-term benefits of the drug and feels its cost-effectiveness is "very unfavorable" and its price a "heavy burden."

As such, unless the company meets a handful of conditions including reducing the price of the drug by 75%, ZIN is reluctant to cover the portfolio.

According to ZIN, Kaftrio costs €194,040 per patient per year, and additional costs in the third year are expected to be €156.4 million, threatening to displace other care, warned ZIN.

Besides a price reduction, ZIN requested that the Netherlands enter into joint price negotiations with other European countries, conclude an agreement outlining appropriate use of Kaftrio and Kalydeco, and ensure long-term data collection to evaluate the safety and efficacy of Vertex's drugs.

In general, however, ZIN is urging the Minister to renegotiate a price agreement for all Vertex's CFTR modulators, including Kaftrio, Kalydeco, Orkambi (lumacaftor/ivacaftor) and Symkevi (tezacaftor/ivacaftor)—as noted by ZIN, "Each new drug turns out to be more expensive than the previous one."

BeNeLuxA Success

The BeNeLuxA Initiative was initially formed in 2015 to promote cross-border collaboration in horizon scanning, information sharing, policy exchange, and HTA by Belgium and the Netherlands. That same year, Luxembourg joined the Initiative, followed by Austria in 2016 and Ireland most recently, in June 2018.

Through BeNeLuxA, participating countries are aiming to increase efficiency of the assessment and pricing and reimbursement of medicines by exchanging expertise, as well as by mutual recognition of HTAs. Importantly in Zolgensma's case, the group engages in joint price negotiations for specific products, in order to try and provide faster and broader patient access.

BeNeLuxA has completed around 15 HTAs and has been most successful with pricing and reimbursement negotiations related to another SMA treatment, Biogen's Spinraza (nusinersen), which came about in July 2018. Following negotiations, Belgium and the Netherlands successfully reached an agreement on the reimbursement of Biogen's SMA treatment.

Despite BeNeLuxA's success in negotiations with Biogen, Ireland's NCPE recommended against reimbursement of Spinraza because of the drug's price.

At the time, Biogen said in a statement: "Biogen provided the HSE with a significant pricing proposal,

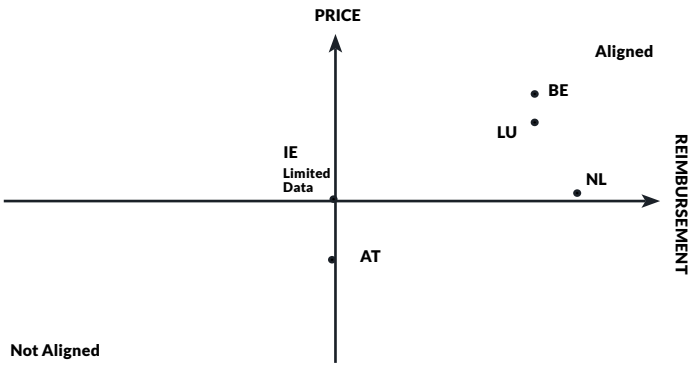
absolutely in line with the final price negotiated in countries aligned with Ireland in the BeNeLuxA initiative, which have each decided to reimburse Spinraza.

Eventually, Irish health regulators examined Spinraza once more after Biogen lowered its asking price and agreed to reimbursement.

Despite the initial issue with reimbursement in Ireland, the Spinraza triumph showed promise for the future of jointly assessing more expensive, innovative medicines – such as Zolgensma.

Alignment Issues

Whilst BeNeLuxA is by far one of the most mature cross-border collaboration efforts, there are nonetheless pricing and reimbursement decision misalignments among participating countries. An inclusive European HTA and pricing negotiation environment offers a multitude of opportunities such as saving time and money, but if the countries cannot agree on various aspects of the process, primarily due to national-level idiosyncrasies, failures can occur.



Country	Distance	Language	Population (millions)	GDP/cap PPP (000s)
AT	Medium	N	8.9	47
BE	Short	Y	11.5	44
NL	Short	Y	17.3	50
LU	Short	Y	0.6	94
IE	Medium	N	4.8	70

Looking at drugs that have been assessed by the group in the past. Common instances of HTA alignment occurred between the core three BeNeLux countries for AstraZeneca's Tagrisso (osimertinib), Pfizer's Vyndaqel (tafamidis), and Ipsen's Xermelo (telotristat ethyl).

Specifically, across the 11 drugs that have been previously assessed, the Netherlands came to positive conclusions the most of all the countries, at 88% of the time, followed by both Luxembourg and Belgium at 75% of the time each. Austria erred on the side of agreement 50% of the time, whereas Ireland joined too recently to draw any sound conclusions. However, as seen in the case of Spinraza, at the national level, Ireland deviated before ultimately deciding to back reimbursement.

With a total population of 43 million across the Initiative, the core group of founding countries - Belgium, the Netherlands and Luxembourg - are seen to be more well aligned, with later entrants Ireland and Austria having less proven alignment or aligning their decisions less often.

The Future of Joint HTA?

"It remains a challenge from a forecasting standpoint to predict exactly what the future dynamics will be on a broad scale," explained Max Kleitmann, EVERSANA Senior Consultant. "However, this also indicates that there is ample opportunity for industry to think creatively and to use innovative new access and pricing models. We see an opportunity for industry to work with authorities to help define the future dynamic."

In this vein, the latest price reduction requests show that the international group is assured that its bargaining power is much stronger collectively than the countries are individually.

As one of Europe's most mature cross-border initiatives, BeNeLuxA and its future success with negotiating access to innovative medicines, such as the final decision on Zolgensma, could be indicative of cross-border collaboration as future standard protocol in Europe.

BeNeLuxA's success in joint negotiation suggests that when certain factors such as language and geography, as well as policy, are aligned, cross-border collaboration has the potential to hold the key to the future of market access.

Rare Disease Company Coalition Forms to Educate Policymakers on Rare Disease Business Model, Experience Bringing Treatments to Market

Date: May 14, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy | Keywords: #acceleron #aeglea #agios #alnylam #harmony #innovation #marketaccess #orchard #orphandrug #orphazyme #r&d #raredisease #rarediseasecompanycoalition #sarepta #taysha #ultragenyx

PRICENTRIC BRIEF:

- The Rare Disease Company Coalition has launched with the aim of informing and educating policymakers on the rare disease company business model, specifically the unique circumstances facing life science companies when developing and bringing to market therapies intended for extremely small and differentiated patient populations
- The Coalition's additional goals include advocating for public policy and regulatory frameworks that account for and recognize the distinct considerations of life science companies operating in the rare disease space; working with policymakers to establish long-term, consistent, equitable and sustainable research incentives for rare diseases and access to the resulting innovation; and increasing awareness of the innovation happening within rare disease companies
- Representing life science companies that brought 22 treatments to market and have 160 rare disease development programs, the Coalition is comprised of founding members Acceleron Pharma, Aeglea BioTherapeutics, Agios Pharmaceuticals, Alnylam Pharmaceuticals, Harmony Biosciences, Orchard Therapeutics, Orphazyme U.S., Inc., Sarepta Therapeutics, Taysha Gene Therapies, and Ultragenyx Pharmaceutical

THE DETAILS

WASHINGTON, D.C., United States – The Rare Disease Company Coalition has launched with the aim of informing and educating policymakers on the rare disease company business model, specifically the unique circumstances facing life science companies when developing and bringing to market therapies intended for extremely small and differentiated patient populations.

Representing life science companies that brought 22 treatments to market and have 160 rare disease development programs, the Coalition is comprised of founding members Acceleron Pharma, Aeglea BioTherapeutics, Agios Pharmaceuticals, Alnylam Pharmaceuticals, Harmony Biosciences, Orchard Therapeutics, Orphazyme U.S., Inc., Sarepta Therapeutics, Taysha Gene Therapies, and Ultragenyx Pharmaceutical.

The education and advocacy-focused group underscored the work accomplished by companies focused on rare diseases—in 2020 alone, Coalition members invested more than $1.4 billion in research and development (R&D), representing about 65% of their annual operating budgets. Further, these companies stated they spend more annually on R&D than revenues generated.

Along with educating policymakers on the experience of bringing orphan drugs to market, the Coalition's goals include advocating for public policy and regulatory frameworks that account for and recognize the distinct considerations of life science companies operating in the rare disease space; working with policymakers to establish long-term, consistent, equitable and sustainable research incentives for rare diseases and access to the resulting innovation; and increasing awareness of the innovation happening within rare disease companies.

Cell & Gene Collective Launches to Raise Awareness of Promises, Challenges of Cell, Gene Therapy

Date: May 20, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Type: Other | Keywords: #access.cellandgenetherapy #astellas #bluebirdbio #bristolmyerssquibb #gilead #hta #kite #nhs #novartis #patientgroup

PRICENTRIC BRIEF:

- Astellas, bluebird bio, Bristol-Myers Squibb (BMS), Kite (a Gilead company), and Novartis have launched the Cell & Gene Collective to raise awareness of the promises and challenges of cell and gene therapies
- The Collective will spearhead the conversation on maintaining the country's early progress and realization of the promise of these therapies, including how to tackle barriers to access and boost public support of these treatments in the NHS
- The Collective has so far undertaken a public survey that found awareness of cell and gene therapy is low, although half of respondents believe they are a good thing, and the Collective held the virtual Patient Advocacy Summit, bringing together patient groups and the industry for a discussion on challenges with these therapies across disease areas

THE DETAILS

LONDON, United Kingdom – Astellas, bluebird bio, Bristol-Myers Squibb (BMS), Kite (a Gilead company), and Novartis have launched the Cell & Gene Collective to raise awareness of the promises and challenges of cell and gene therapies.

In the UK, the Collective will spearhead the conversation on maintaining the country's early progress and realization of the promise of these therapies, including how to tackle barriers to access and boost public support of these treatments in the NHS. As it stands, cell and gene therapies go through the same value assessment as less complex medicines in the UK, and the infrastructure needed to support their administration isn't widely available.

The Collective has so far undertaken a public survey that found awareness of cell and gene therapy is low, although half of respondents believe they are a good thing.

Additionally, the Collective held the virtual Patient Advocacy Summit, bringing together patient groups and the industry for a discussion on challenges with these therapies across disease areas.

Bob Roosjen, Interim General Manager at Gilead UK & Ireland, stated, "We're pleased to be launching the Cell & Gene Collective alongside Novartis, Bristol Myers Squibb, Astellas and bluebird bio. Together we're committed to ensuring patients in the UK who can benefit from transformational cell and gene treatments do so, and that people have a clear understanding of how these therapies work. Cell and gene therapies aim to transform patients' lives, now let's work together to get the NHS ready for the future."

Nevada's Drug Price Transparency Bill Up for Permanent Funding

Date: May 19, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy, Price Changes | Keywords: #database #diabetes #hhs #pbm #pharmacy #priceincrese #pricetransparency #sb380 #wholesale

PRICENTRIC BRIEF:

- This week, Nevada's Senate Finance Committee considered a $780,000 fiscal note from the Department of Health and Human Services (HHS) to fund the transfer of the existing state drug pricing database to the Enterprise Information Technology Services Division, where it would be managed by a pharmacist, with support from a management analyst, as part of SB380
- Expanding on two bills from 2017 and 2019 that targeted price increase for diabetes and asthma drugs, respectively, SB380 would require manufacturers of all drugs, regardless of the disease they target, that exceed a $40 list prices for a course of therapy and saw a 10% increase during the previous calendar year to report certain costs and profits associated with the production of the drugs
- Further, the bill would have prescription drug wholesalers report to the state certain data points for drugs with a list price exceeding $40 for a course of therapy, including minimum and maximum list prices of the drug over the last year and the aggregate amount of rebates negotiated with drug companies, manufacturers, and pharmacy benefit managers (PBMs)

THE DETAILS

CARSON CITY, NV, United States – This week, Nevada's Senate Finance Committee considered a $780,000 fiscal note from the Department of Health and Human Services (HHS) to fund a measure under SB380 that aims to transfer the existing state drug pricing database to the Enterprise Information Technology Services Division, where it would be managed by a pharmacist, with support from a management analyst.

Expanding on two bills from 2017 and 2019 that targeted price increase for diabetes and asthma drugs, respectively, SB380 would require manufacturers of all drugs, regardless of the disease they target, that exceed a $40 list prices for a course of therapy and saw a 10% increase during the previous calendar year to report certain costs and profits associated with the production of the drugs.

Further, for drugs with a list price exceeding $40 for a course of therapy, the bill would have prescription drug wholesalers report to the state minimum and maximum list prices of the drug over the last year and the aggregate amount of rebates negotiated with drug companies, manufacturers, and pharmacy benefit managers (PBMs).

The Finance Committee and HHS considered using penalties and fees collected from the diabetes and asthma programs when companies failed to meet reporting requirements; however, these funds were initially planned to go toward diabetes and asthma education programs. For SB380 sponsor Senator Julia Ratti, the use of these penalties and fees to fund management of the transparency database is a good start, but a more concrete solution is necessary.

Ratti commented, "The Department of Health and Human Services has been doing yeoman's work to fulfill the NRS around transparency reporting…but the resources haven't necessarily been there to do the robust analysis and the robust reporting with the data we have available. With this bill, we requested the unsolicited fiscal note to really look at, what would it cost to implement our drug transparency program in a sustainable way where we're not taking a little bit of somebody's time over here and a little bit of somebody's time over there."

Connecticut Bill H.B. 6447 Penalizes Companies Who Raise Drug Price More Than Inflation Plus 2%

Date: May 21, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy | Keywords: #cbia #connecticutcoverageprogram #hb6447 #healthinsurance #inflation #innovation #oopspending #penalty #pricechange #savings

PRICENTRIC BRIEF:

- Connecticut Governor Ned Lamont has recently introduced H.B. 6447, "An Act Creating the Covered Connecticut Program to Expand Access to Affordable Health Care," that will limit annual increases in drug prices to more than inflation plus 2% and fine companies who breach this benchmark a penalty equal to 80% of the excess drug cost
- Simultaneously, H.B. 6447 offers more coverage to Connecticuters through the Covered Connecticut Program, which will be funded with $50 million a year from assessments of health insurance companies and penalties collected from pharmaceutical companies that violate price increase limits
- In response, the Connecticut Business and Industry Association (CBIA) spearheaded a letter along with 20 biotech and pharmaceutical companies and industry organizations advising Gov. Lamont against price controls for medicines, stating: "In countries that artificially set prices, shortages occur frequently, fewer drugs are available, and the newest medicines are slow to come on the market"

THE DETAILS

HARTFORD, CT, United States – Connecticut Governor Ned Lamont has recently introduced H.B. 6447, "An Act Creating the Covered Connecticut Program to Expand Access to Affordable Health Care," that will limit annual increases in drug prices to more than inflation plus 2% and fine companies who breach this benchmark a penalty equal to 80% of the excess drug cost.

The governor cited the results of a Kaiser Family Foundation analysis in which it was found that over half of the drugs studied experienced price increases above the rate of inflation in 2018-2019. For Lamont, the costs of drugs are increasing "on a scale that Connecticut can't afford," the governor adding that a health care cost growth benchmark could bring more transparency to across increases across the sector.

Simultaneously, H.B. 6447 offers more coverage to Connecticuters through the Covered Connecticut Program, which will be funded with $50 million a year from assessments of health insurance companies and penalties collected from pharmaceutical companies that violate price increase limits.

In response, the Connecticut Business and Industry Association (CBIA) wrote a letter along with 20 biotech and pharmaceutical companies and industry organizations advising Gov. Lamont against price controls for medicines. Reiterating the industry's previous position on initiatives, both at the federal and state level, to introduce stricter price controls, CBIA stated: "In countries that artificially set prices, shortages occur frequently, fewer drugs are available, and the newest medicines are slow to come on the market."

CBIA and its associates warned that such price controls will stifle innovation, and that the focus on drug pricing is misguided, given that 85% to 90% of healthcare costs go towards something other than drugs. Instead, patients need concrete reforms that help them save on drugs at the counter, including more predictable monthly costs, cost-sharing assistance to lower out-of-pocket (OOP) spending, and negotiated savings need to be shared with customers.

Prescription Pricing for the People Act Directs Federal Trade Commission to Target PBMs

Date: May 21, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy | Keywords: #competition #federaltradecommission #formulary #medicaid #medicare #pbm #pharmacy #prescriptionpricingforthepeopleact #pricingandreimbursement #rebate

PRICENTRIC BRIEF:

- Under the Prescription Pricing for the People Act, the Federal Trade Commission (FTC) will study the role and recent merger activity of pharmacy benefit managers (PBMs) to examine the effects of consolidation on pricing and potentially anticompetitive behavior, which will guide policy recommendations from Congress to improve the area and protect consumers
- Specifically, the FTC will check whether PBMs charge certain payers, including Medicare and Medicaid, a higher price than reimbursement rates for competing pharmacies while reimbursing pharmacies in which the PBMs have an ownership interest at the rate charged to payers; steer patients to pharmacies in which the PBM has an ownership stake; audit or review proprietary data of pharmacies not owned by the PBM and use such data for competitive advantage; and use formulary designs to depress the market share of low-cost, lower rebate prescription drugs
- Amidst the congressional drug pricing legislation saga over the last few years, Grassley has been a vocal critic against enacting price controls in the U.S., instead favoring interventions that save consumers money through select price caps and initiatives to boost competition

THE DETAILS

WASHINGTON, D.C., United States – Under the Prescription Pricing for the People Act, the Federal Trade Commission (FTC) will study the role and recent merger activity of pharmacy benefit managers (PBMs) to examine the effects of consolidation on pricing and potentially anticompetitive behavior, which will guide policy recommendations from Congress to improve the area and protect consumers.

Senator Chuck Grassley (R-Iowa), who co-introduced the Act will Senator Maria Cantwell (D-Washington), commented, "PBMs play a significant role in determining how much patients and the government pay for prescriptions. Much of their business model is cloaked in secrecy, and the industry has experienced significant consolidation in recent years. Our bill will provide Congress with a better understanding of the PBM industry, so any future legislation can better protect patients and safeguard competition."

Specifically, the FTC will check whether PBMs charge certain payers, including Medicare and Medicaid, a higher price than reimbursement rates for competing pharmacies while reimbursing pharmacies in which the PBMs have an ownership interest at the rate charged to payers; steer patients to pharmacies in which the PBM has an ownership stake; audit or review proprietary data of pharmacies not owned by the PBM and use such data for competitive advantage; and use formulary designs to depress the market share of low-cost, lower rebate prescription drugs.

In addition, the FTC's investigation will highlight trends or observations on the state of competition among PBMs and legal or regulatory obstacles that need to be enforced to protect consumers, as well as whether more information regarding the roles of intermediaries would benefit consumers.

Amidst the congressional drug pricing legislation saga over the last few years, Grassley has been a vocal critic against enacting price controls in the U.S., instead favoring interventions that save consumers money through select price caps and initiatives to boost competition. While former U.S. President Donald Trump issued the Most-Favored Nations (MFN) rule to benchmark drug prices in the U.S. based on those found in economically similar countries, he preferred Grassley's previous legislation over U.S. Speaker of the House Nancy Pelosi's H.R. 3, which would've institutionalized a form of reference pricing in the U.S.

Further, as policymakers have sought to introduce price controls, the pharmaceutical industry has continued to direct attention to PBMs and health insurers, blaming this side of the healthcare system for high costs for patients.

Province of Alberta Expands Biosimilar Switching Program to Include Humira (Adalimumab)

Date: May 14, 2021 | Country: CANADA-ALBERTA | Region: NORTH AMERICA | Type: Biosimilar, Regulation | Keywords: #adalimumab #biologic #biosimilar #humira #program #switching
PRICENTRIC BRIEF:

- The Province of Alberta has expanded its biosimilar switching program to include AbbVie's Humira (adalimumab) which is taken by approximately 3,300 Albertans
- These patients will switch to one of five adalimumab biosimilars over the next year beginning on May 1, with savings feeding into investments in the health system, according to Alberta Health
- Adalimumab biosimilars just entered the Canadian market in mid-February, and all three provincial switching policies, in Alberta, British Columbia and New Brunswick, now require patients to switch from Humira to a biosimilar

THE DETAILS

EDMONTON, Alberta, Canada — The Province of Alberta has expanded its biosimilar switching program to include AbbVie's Humira (adalimumab).

Approximately 3,300 patients taking the biologic Humira will switch to one of five adalimumab biosimilars over the next year beginning on May 1, with savings feeding into investments in the health system, according to Alberta Health.

"Biosimilars Canada congratulates the Province of Alberta and Health Minister Tyler Shandro for continuing to expand the use of biosimilars in the province to manage costs, ensure the sustainability of the drug program and fund innovative new therapies," said Jim Keon, President of Biosimilars Canada.

Adalimumab is used in the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa, plaque psoriasis, and psoriatic arthritis.

Adalimumab biosimilars just entered the Canadian market in mid-February, and all three provincial switching policies, in Alberta, British Columbia and New Brunswick, now require patients to switch from Humira to a biosimilar.

British Columbia and Alberta implemented biosimilar switching policies in 2019 and New Brunswick announced a policy last month.

When Alberta announced its biosimilar switching policy in December 2019, it said spending on biologics had swelled from CA$21 million to CA$ 238 million over 10 years.

Tyler Shandro, Alberta's Minister of Health, expects Alberta to save between CA$227 million and CA$380 million over the next four years thanks to the Initiative.

Alberta originally intended to switch those on government-sponsored drug plans who were prescribed a biologic drug to a biosimilar by July 2020, but this switch was mostly pushed to 2021 due to the coronavirus pandemic.

Nevertheless, in November 2020, it was announced at Terrapinn's Festival of Biologics that Alberta had already switched 16% of patients from seven reference products to their respective biosimilars.

The initial list of branded drugs impacted by the switch included Enbrel (etanercept), Remicade (infliximab), Lantus (insulin glargine), Neupogen (filgrastim), Neulasta (pegfilgrastim), Rituxan (rituximab), or, although not a biologic, Copaxone (glatiramer).

Switching is not mandatory; patients can file exemption requests to remain on their branded product but will be subject to out-of-pocket (OOP) payments.

Quebec to Switch Patients to Biosimilars by April 2022

Date: May 20, 2021 | Country: CANADA-QUEBEC | Region: NORTH AMERICA | Type: Biosimilar | Keywords: #generalprescriptiondruginsuranceplan #healthandsocialservices #inesss #savings #switching

PRICENTRIC BRIEF:

- Quebec's Minister of Health and Social Services, Christian Dube has announced that Quebec will start using more biosimilar drugs to generate annual savings of over CAD 100 million to reinvest in boosting access to innovative therapies
- Before Quebec, other Canadian provinces British Columbia, Alberta, and New Brunswick implemented biosimilar switching policies targeting patients on provincial drug plans living with diseases such as inflammatory arthritis, inflammatory bowel disease, diabetes, and psoriasis, who are taking drugs such as Janssen's Remicade (infliximab) and AbbVie's Humira (adalimumab), to name a couple
- Quebec will soon cover only (with a few exceptions) biosimilar drugs on the General Prescription Drug Insurance Plan (RGAM) list of medicines, and patients taking a reference biologic drug will have to switch to a biosimilar by April 1, 2022

THE DETAILS

QUEBEC CITY, Canada – Quebec's Minister of Health and Social Services, Christian Dube has announced that Quebec will start using more biosimilar drugs to generate annual savings of over CAD 100 million to reinvest in boosting access to innovative therapies.

Before Quebec, other Canadian provinces British Columbia, Alberta, and New Brunswick implemented biosimilar switching policies targeting patients on provincial drug plans living with diseases such as inflammatory arthritis, inflammatory bowel disease, diabetes, and psoriasis, who are taking drugs such as Janssen's Remicade (infliximab) and AbbVie's Humira (adalimumab), to name a couple.

As with Canada's other like-minded provinces, Quebec seeks to improve the use of biosimilars, as they are "significantly less expensive than reference drugs." Over the years, Quebec's National Institute of Excellence in Health and Social Services (INESSS) has issued recommendations for several biosimilar drugs, however they remain unused.

Quebec will soon cover only (with a few exceptions) biosimilar drugs on the General Prescription Drug Insurance Plan (RGAM) list of medicines, and patients taking a reference biologic drug will have to switch to a biosimilar by April 1, 2022.

Dube commented, "Innovation is giving rise to incredible medical advances and the development of healthcare practices and offers that are always better suited to people's needs. The decisive shift we are taking towards the judicious use of biosimilar drugs is a good example of this. I am convinced that this will help ensure the sustainability and viability of our health system. We have the health of the population at heart and the actions taken in this matter are in the interest and for the benefit of patients."

CADTH Publishes Report Examining Gaps in Provincial Coverage of Oncology Medicines

Date: May 6, 2021 | Country: CANADA-ALBERTA, CANADA-MANITOBA, CANADA-NEWFOUNDLAND & LABRADOR, CANADA-ONTARIO, CANADA-QUEBEC, CANADA-SASKATCHEWAN, CANADA-YUKON | Region: NORTH AMERICA | Type: Pricing & Reimbursement | Keywords: #cadth #formulary #oncology #pmprb #provincial #report

PRICENTRIC BRIEF:

- The Canadian Agency for Drugs and Technologies in Health (CADTH) has published a report on the coverage of oncology medicines by provincial formularies across the country, the second report of a series of three analyses examining overlaps and gaps of coverage between the formularies
- Oncology medicines administered in Canadian hospitals are fully covered by hospital budgets and provided at no cost to the patient but take-home oncology medicines, an emerging standard treatment for many cancers, are not consistently covered by public drug programs in Canada which may cause payer split between jurisdictions
- Provinces with the highest per capita spending on hospital oncology medicines also ranked among the top spenders for take-home medicines—Oncology medicines accounted for a considerably smaller portion of private drug plan spending (3.8%) than in the combined public/ private sector (9.9%)

THE DETAILS

OTTAWA, ON, Canada — The Canadian Agency for Drugs and Technologies in Health (CADTH) has published a report on the coverage of oncology medicines by provincial formularies across the country, the second report of a series of three analyses examining overlaps and gaps of coverage between the formularies.

The three reports aim to inform discussions on the development of a national formulary, which has been identified as a keystone in ensuring equitable access and achieving better drug prices for Canadians.

The first report provided insight into the degree of alignment between the general public drug plan

formularies and the third report will analyze newer medicines assessed through CADTH's Common Drug Review (CDR) process.

The second and newly published report addresses the public coverage of oncology medicines reviewed by the Canadian Agency for Drugs and Technologies in Health's (CADTH) interim Joint Oncology Drug Review (iJODR) or pan-Canadian Oncology Drug Review (pCODR), as of the end of March 2020.

It also looks at specific oncology market segments, including hospital and take-home, biologic and small molecule, and single- and multi-source medicines.

The report found that provinces listed an average of 84% of the selected medicines at the medicinal ingredient level. Of the 87 selected medicines, 88% were listed in six or more provinces, accounting for 98% of national sales.

Coverage rates were also comparable for all indications analyzed and listing agreement rates across provincial formularies were high, with identical rates at the indication level. Public formulary listing rates are consistently high across all oncology market segments analyzed.

Oncology medicines administered in Canadian hospitals are fully covered by hospital budgets and provided at no cost to the patient but take-home oncology medicines, an emerging standard treatment for many cancers, are not consistently covered by public drug programs in Canada which may cause payer split between jurisdictions.

There are some sizable differences in overall provincial spending and payer split for the selected oncology medicines in the report.

Provinces with the highest per capita spending on hospital oncology medicines also ranked among the top spenders for take-home medicines. Oncology medicines accounted for a considerably smaller portion of private drug plan spending (3.8%) than in the combined public/ private sector (9.9%).

Privately insured patients paid more for their take-home oncology medicines than beneficiaries in the public drug plans overall, though the patient-paid share of costs differed significantly among the public drug plans.

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Latuda First Drug Recommended Under Wales' New Appraisal for Medicines with License Extensions

Date: May 13, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Type: HTA, Policy | Keywords: #awmsg #awttc #drugapproval #licenseextension #newmedicinesgroup #nice #pediatric

PRICENTRIC BRIEF:

- The All Wales Medicines Strategy Group (AWMSG) has announced that Sunovion's Latuda (lurasidone) for the treatment of schizophrenia in adolescents aged 13 to 17 years was the first medicine to pass through the agency's new process for appraising medicines that have had their license extended to include use in children and young people under 18 years
- For a medicine to be considered by AWMSG under this new process implemented in December 2020, its license extension must be for patients under 18 years, it must be accepted for use in adults by AWMSG or its English counterpart, the National Institute for Health and Care Excellence (NICE), and the license extension must match the adult indication in which it was approved, in every respect except for the target age group of patients
- Once a medicine meets these criteria, the All Wales Therapeutics and Toxicology Center (AWTTC) prepares an assessment and draft recommendation for AWMSG consideration, with the recommendation anticipated to be issued more quickly than has been the case with full or limited submissions

THE DETAILS

CARDIFF, United Kingdom – The All Wales Medicines Strategy Group (AWMSG) has announced that Sunovion's Latuda (lurasidone) for the treatment of schizophrenia in adolescents aged 13 to 17 years was the first medicine to pass through the agency's new process for appraising medicines that have had their license extended to include use in children and young people under 18 years.

Latuda was initially recommended in 2015 for the treatment of schizophrenia in adults, but the AWMSG has recommended it be accessible to children 12 to 17 years, thus extending use of Latuda for a younger population.

AWMSG implemented its new process in December 2020, with the hope of a simplified process resulting in improved access to licensed medicines for children and adolescents in Wales. For a medicine to be considered by AWMSG under this new process implemented in December 2020, its license extension must be for patients under 18 years, it must be accepted for use in adults by AWMSG or its English counterpart, the National Institute for Health and Care Excellence (NICE), and the license extension must match the adult indication in which it was approved, in every respect except for the target age group of patients.

Once a medicine meets these criteria, the All Wales Therapeutics and Toxicology Center (AWTTC) prepares an assessment and draft recommendation for AWMSG consideration. As medicines appraised under this process are not subject to New Medicines Group assessment, a recommendation is anticipated to be issued more quickly than has been the case with full or limited submissions.

Scotland's SNP Poised to Launch National Pharmacy Agency, Boost Investment in Manufacturing

Date: May 12, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Type: Policy | Keywords: #cancerdiagnosticcenter #funding #generic #manufacture #nationalpharmacyagency #nhsscotland #nhstayside #prescriptionfee #regulation #specialmedicinecosteffectiveness #sustainability

PRICENTRIC BRIEF:

- In the recent parliamentary election, the Scottish National Party (SNP) won 64 seats in the Scottish Parliament, thus paving the way for increased funding for the NHS and the establishment of the National Pharmacy Agency (NPA), as was promised in the SNP Manifesto
- The NPA will make sure medicines are safe and of high quality, at the most-cost effective price, while simultaneously, where possible, establishing expanded manufacturing capabilities for both generic and "special" medicines, and work with the Scottish Investment Bank to support cutting edge research and development (R&D) to bring new medicines to Scotland
- Other measures include the NHS Center for Sustainable Delivery pioneering and delivering new, better, and more sustainable ways of working across the NHS to fully harness the potential of new treatments, and the Government establishing a fast-track cancer diagnostic center in every health board area, the first three of which will be up and running by the month's end

THE DETAILS

EDINBURGH, Scotland – In the recent parliamentary election, the Scottish National Party (SNP) won 64 seats in the Scottish Parliament, thus paving the way for increased funding for the NHS and the establishment of the National Pharmacy Agency (NPA), as was promised in the SNP Manifesto.

Most notably, the NPA will make sure medicines are safe and of high quality, at the most-cost effective price, while simultaneously, where possible, establishing expanded manufacturing capabilities for both generic and "special" medicines—already, NHS Tayside currently manufactures small batches of generics and special medicines.

Further, the NPA will work with the Scottish Investment Bank to support cutting edge research and development (R&D) to bring new medicines to Scotland.

The NHS Center for Sustainable Delivery will pioneer and deliver new, better, and more sustainable ways of working across the NHS to fully harness the potential of new treatments, and the Government will establish a fast-track cancer diagnostic center in every health board area, the first three of which will be up and running by the month's end.

The NHS will receive a funding boost of 20% for COVID-19 recovery, with £2.5 billion for frontline services. Scotland's NHS Recovery Plan will see the restoration of paused services and swifter delivery of urgent care, while catching up with any delays in treatments. Additional measures including nixing NHS dentistry charges, protecting free prescriptions, and a 10-year investment in refurbishing NHS facilities.

NICE Extends Clinical Eligibility Criteria for Spinraza

Date: May 5, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Type: Breaking News, HTA, Pricing & Reimbursement | Keywords: #datacollection #maa #managedaccess #nhs #nursinursen #pricing #reimbursement #sma #spinraza

PRICENTRIC BRIEF:

- The National Institute for Health and Care Excellence (NICE) has completed its review of data collected on Spinraza (nursinersen) as part of the therapy's Managed Access Agreement (MAA)
- The Biogen drug, which is used for spinal muscular atrophy (SMA), will now be available to more patients than it previously was, following new evidence that supports a change in the MAA treatment eligibility criteria
- The MAA was initially set up between NICE, NHS England, NHS Improvement, and Biogen to allow patients to access Spinraza while data can be collected to gauge its impact in certain groups for whom additional evidence is required to address uncertainties

THE DETAILS

LONDON, United Kingdom – The National Institute for Health and Care Excellence (NICE) has completed its review of data collected on Spinraza (nursinersen) as part of the therapy's Managed Access Agreement (MAA).

The Biogen drug, which is used for spinal muscular atrophy (SMA), will now be available to more patients than it previously was, following new evidence that supports a change in the MAA treatment eligibility criteria.

Specifically, the review assessed whether people with type III SMA who are unable to walk can benefit from Spinraza and therefore should be included in the MAA.

Meindert Boysen, deputy chief executive and director of the Centre for Health Technology Assessment at NICE, explained the extension of eligibility: "There are people with SMA who are not able to access treatment with nusinersen under the terms of the MAA which began in July 2019."

"At the time we made a commitment that we would review new evidence on the potential benefits of nusinersen for type III SMA patients who are not currently receiving it. We are therefore pleased that the review has concluded that it is appropriate to extend the clinical eligibility criteria to allow access to nusinersen for type III SMA patients who aren't able to walk. It will also allow the removal of the rule which meant that patients who had lost the ability to walk needed to regain that ability within 12 months of treatment in order to be eligible for further treatment."

The MAA review involved Biogen, patient groups, clinicians, SMA REACH UK, NHS England, and NHS Improvement.

The MAA was initially set up between NICE, NHS England, NHS Improvement, and Biogen to allow patients to access Spinraza while data can be collected to gauge its impact in certain groups for whom additional evidence is required to address uncertainties.

Spinraza MAA "One of Most Comprehensive in the World"

In May 2019, it was announced that NHS England would be funding Spinraza for pediatric patients, whereas treatment for patients with SMA types 2 and 3 would be administered once services were established.

Under the deal, which NHS called "one of the most comprehensive in the world," patients with SMA types 1, 2, 3a, and 3b, including adults and siblings who have yet shown symptoms, should benefit from Spinraza.

The Spinraza MAA allows funding for Biogen's drug while further data can be collected. The MAA was part of NHS' Long Term Plan, which seeks to secure a string of "smart deals" to ensure investment in world-class innovative technologies while making sure patients access new treatments.

France Favors Reimbursement for CAR-T Therapy Tecartus in R/R MCL

Date: May 13, 2021 | Country: FRANCE | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #ansm #atu #carttherapy #cellandgenetherapy #conditionalmarketingauthorization #earlyaccess #europeancommission #gilead #has #kite #transparencycommittee

PRICENTRIC BRIEF:

- France's High Health Authority (HAS) has issued a favorable opinion regarding reimbursement for Gilead/Kite's Tecartus (brexucabtagene autoleucel) for the treatment of adult patients with relapsed or refractory (R/R) mantle cell lymphoma (MCL) after two lines of systemic treatment, including with a Bruton's tyrosine kinase (BTK) inhibitor
- In December 2020, the European Commission granted conditional marketing authorization to Tecartus and the National Agency for Medicines and Health Products Safety (ANSM) announced the commencement of a cohort authorized temporary use (ATU) scheme for the CAR-T therapy
- Tecartus was found to render important medical service, as well as moderate improvement in actual benefit (ASMR III), with HAS considering relevant short-term efficacy data from the non-comparative Phase 2 ZUMA-2 study, as well as uncertainties about the duration of Tecartus' effect, significant short-term toxicity, and the absence of long-term safety data

THE DETAILS

PARIS, France – France's High Health Authority (HAS) has issued a favorable opinion regarding reimbursement for Gilead/Kite's Tecartus (brexucabtagene autoleucel) for the treatment of adult patients with relapsed or refractory (R/R) mantle cell lymphoma (MCL) after two lines of systemic treatment, including with a Bruton's tyrosine kinase (BTK) inhibitor.

Tecartus received conditional marketing authorization from the European Commission in mid-December of 2020 for the treatment of adult patients with R/R MCL after two or more lines of systemic therapy, including a BTK inhibitor.

That same month, the National Agency for Medicines and Health Products Safety (ANSM) announced the commencement of a cohort authorized temporary use (ATU) scheme for Tecartus.

Under the ATU, Gilead was required to every three months provide ANSM with an inventory of patients and issues with adverse events (AEs) and, once the ATU is wrapped, the company was to additionally submit two summary reports detailing all data collected relevant to patient characteristics, actual modalities of the drug's use, efficacy, and pharmacovigilance, as well as any undesirable effects.

According to HAS, the use of Tecartus is limited to treatment centers qualified in CAR-T therapies.

Tecartus was found to render important medical service, as well as moderate improvement in actual benefit (ASMR III). To reach this conclusion's, HAS' Transparency Committee considered relevant short-term efficacy data from the non-comparative Phase 2 ZUMA-2 study in terms of complete response (approximately and overall survival, in life-threatening clinical situations for which the treatment options are limited and do not allow to consider prolonged remission as observed.

However, HAS also considered uncertainties about the breadth of Tecartus' effect due to a lack of direct comparison with the usual treatment and the limits of the indirect comparisons made, uncertainties about maintaining long-term clinical efficacy—in particular, about obtaining cures in patients in lasting remission—, significant short-term toxicity, and the absence of long-term safety data.

Spain's AESEG Proposes National Reindustrialization to Promote Greater Generic Use

Date: May 12, 2021 | Country: SPAIN | Region: EUROPE | Type: Regulation | Keywords: #aefi #aemps #aeseg #covid19 #drugshortage #drugsupply #essentialmedicine #generic #manufacture #sustainability

PRICENTRIC BRIEF:

- As generic drugs have been crucial to Spain's efforts to fight COVID-19, AESEG's Coordinator of Regulatory Affairs Maria Alvarez Fernandez at the 40th symposium of the Spanish Association of Industry Pharmacists (AEFI) shared the challenges Spain's generic industry has faced during the pandemic to set a clear path forward for the future
- Committing to greater use of generics, AESEG underscored the need for a national reindustrialization, urging an investment of 700 million euros in a plan that curbs risk, ensures minimum profitability thresholds for essential generics, and promotes national manufacturing by betting on existing manufacturing plants, among other initiatives
- For AESEG, generics are essential to Spain's health system (SSN) because they ensure access to medicines, including the supply of medicines, and promote sustainability

THE DETAILS

MADRID, Spain – Amid the COVID-19 Pandemic, the Ministry of Health put together a list of medicines considered to be essential for combatting COVID-19, including antibiotics and drugs for asthma and chronic obstructive pulmonary disorder (COPD), among others, and the Spanish Agency for Medicines and Health Products (AEMPS) has since been reviewing Spain's inventory.

However, according to the Spanish Association of Generic Medicines (AESEG), there is no general drug list exclusively for the treatment of COVID-19, as the list prepared by AEMPS includes medicines used in ICUs and some drugs that can be purchased at the pharmacy, many of which are not specifically for COVID-19 and are generics.

As generic drugs have been crucial to Spain's efforts to fight COVID-19, AESEG's Coordinator of Regulatory Affairs Maria Alvarez Fernandez at the 40th symposium of the Spanish Association of Industry Pharmacists (AEFI) shared the challenges Spain's generic industry has faced during the pandemic to set a clear path forward for the future.

Fernandez explained that, of the drugs declared essential by AEMPS for fighting COVID-19, 70% have a generic alternative, and Spain's 13 domestic generic manufacturing plants have been working "at full capacity and in collaboration with AEMPS" to meet patient demand. But Europe has been seeking beyond its borders for generic drug manufacturing—as it stands, Europe only has 33% of active pharmaceutical ingredient (API) authorizations.

Committing to greater use of generics, AESEG underscored the need for a national reindustrialization, urging an investment of 700 million euros in a plan that encourages the free participation of all companies to avoid the risk of shortages; ensures minimum profitability thresholds for so-called essential products; promotes national manufacturing by betting on existing manufacturing plants; reduces the administrative burden of laboratories through the introduction of digital tools and in exceptional cases apply the regulatory flexibility that has given such good results with COVID-19 products; reviews the competition system to include other criteria (in addition to the price) in the purchase of medicines; improves the management of stocks in hospitals to be able to adapt manufacturing to real needs and not to throw away product; and helps coordinate between authorities to eliminate duplications.

For AESEG, generics are essential to Spain's health system (SSN) because they ensure access to medicines, including the supply of medicines, and promote sustainability.

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ZIN Rejects Kaftrio Plus Kalydeco, Urges 75% Price Reduction and Renegotiation of All Vertex Drugs

Date: May 6, 2021 | Country: NETHERLANDS | Region: EUROPE | Type: Pricing & Reimbursement | Keywords: #cftrmodulator #costeffectiveness #datacollection #gvs #ministerofmedicalcare #vertex #negotiaion #pediatric #zorginstituut

PRICENTRIC BRIEF:

- The Zorginstituut (ZIN) has advised the Minister of Medical Care to exclude Vertex's triple-combination therapy Kaftrio (elexacaftor/tezacaftor/ivacaftor) plus Kalydeco (ivacaftor) from the Medicines Reimbursement System (GVS) unless the company meets a handful of conditions, including reducing the price of the drug by 75% and monitoring its long-term efficacy
- While ZIN is confident in the effect of Kaftrio and Kalydeco, especially when it comes to improving lung function and reducing respiratory complaints, the agency is uncertain of the long-term benefits of the drug and feels its cost-effectiveness is "very unfavorable" and its price a "heavy burden"
- In general, however, ZIN is urging the Minister to renegotiate a price agreement for all Vertex's CFTR modulators, including Kaftrio, Kalydeco, Orkambi (lumacaftor/ivacaftor) and Symkevi (tezacaftor/ivacaftor)—as noted by ZIN, "Each new drug turns out to be more expensive than the previous one"

THE DETAILS

AMSTERDAM, Netherlands – The Zorginstituut (ZIN) has advised the Minister of Medical Care to exclude Vertex's triple-combination therapy Kaftrio (elexacaftor/tezacaftor/ivacaftor) plus Kalydeco (ivacaftor) from the Medicines Reimbursement System (GVS) unless the company meets a handful of conditions, including reducing the price of the drug by 75%.

While ZIN is confident in the effect of Kaftrio and Kalydeco, especially when it comes to improving lung function and reducing respiratory complaints, the agency is uncertain of the long-term benefits of the drug and feels its cost-effectiveness is "very unfavorable" and its price a "heavy burden." According to ZIN, Kaftrio costs €194,040 per patient per year, and additional costs in the third year are expected to be €156.4 million, threatening to displace other care, warned ZIN.

Besides a price reduction, ZIN requested that the Netherlands enter into joint price negotiations with other European countries, conclude an agreement outlining appropriate use of Kaftrio and Kalydeco, and ensure long-term data collection to evaluate the safety and efficacy of Vertex's drugs.

In general, however, ZIN is urging the Minister to renegotiate a price agreement for all Vertex's CFTR modulators, including Kaftrio, Kalydeco, Orkambi (lumacaftor/ivacaftor) and Symkevi (tezacaftor/ivacaftor)—as noted by ZIN, "Each new drug turns out to be more expensive than the previous one."

TLV to Explore Outcome-Based Payments, Upgraded Health Economic Assessments for Precision Medicine, ATMPs

Date: May 4, 2021 | Country: SWEDEN | Region: EUROPE | Type: HTA, Pricing & Reimbursement | Keywords: #atmp #cellandgenetherapy #healtheconomicanalysis #innovation #innovativepaymentmodel #outcomesbasedpayment #precisionmedicine #tlv #valuebasedpricing

PRICENTRIC BRIEF:

- In "Health Economic Aspects of Precision Medicine and ATMP," the Swedish Dental and Pharmaceutical Benefits Agency (TLV) has outlined central challenges in evaluating and paying for advanced therapy medicinal products (ATMPs), and offered suggestions to mitigate any concerns, specifically regarding the lack of long-term evidence the high upfront prices
- TLV has supported value-based pricing for products that are used in combination with other products and ways in which the agency can capture the patient benefit provided by precision medicine and ATMPs in its health economic evaluations, while considering the uncertainty surrounding the extent of the benefit and how long it lasts
- General-Director of TLV Agneta Karlsson said, "We believe that outcome-based payment models should be tested, where payment takes place when society sees the actual benefit of treatment," adding that the agency will set conditions for new payment models, at first through a pilot

THE DETAILS

STOCKHOLM, Sweden – In "Health Economic Aspects of Precision Medicine and ATMP," the Swedish Dental and Pharmaceutical Benefits Agency (TLV) has outlined central challenges in evaluating and paying for advanced therapy medicinal products (ATMPs), and offered suggestions to mitigate any concerns, specifically regarding the lack of long-term evidence the high upfront prices.

While precision medicines and ATMPs have offered hope for many patients suffering from severe diseases, TLV noted that, simultaneously, not all these new technologies offer a clear benefit and are worth their price.

According to Agneta Karlsson, Director General of TLV, "These treatments are in many ways revolutionary and can cure or alleviate serious illnesses. At the same time, our starting point must be that we must, as always, value health benefits and reasonable costs in order for our common resources to suffice. Which new technologies and products are to be used must therefore be carefully considered."

TLV has supported value-based pricing for products that are used in combination with other products and ways in which the agency can capture the patient benefit provided by precision medicine and ATMPs in its health economic evaluations, while considering the uncertainty surrounding the extent of the benefit and how long it lasts.

Karlsson said, "We believe that outcome-based payment models should be tested, where payment takes place when society sees the actual benefit of treatment," adding that they will reduce the payer's risk, despite being "complicated to apply." TLV will continue to work to develop health economic assessments better suited for precision medicine and ATMPs, as well as setting conditions for new payment models, at first through a pilot.

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Denmark Requests Zolgensma's Price Reflects Uncertainty Surrounding Long-Term Efficacy

Date: May 4, 2021 | Country: DENMARK | Region: EUROPE | Type: HTA, Pricing & Reimbursement | Keywords: #amgros #biogen #cellandgenetherapy #danishmedicinescouncil #data #negotiation #novartis

PRICENTRIC BRIEF:

- The Danish Medicines Council has concluded that Novartis' Zolgensma (onasemnogene abeparvovec) works just as well as Biogen's Spinraza (nusinersen) in infants with spinal muscular atrophy (SMA) and has requested that Novartis provide further documentation of the gene therapy's efficacy and set a price that considers the uncertainty about its effect
- The Council's review of Zolgensma is based on studies involving infants with Type 1 SMA who were under six months of age when they received treatment and infants who were born with SMA but hadn't yet expressed symptoms—However, there are no studies on Zolgensma in older children or those with Types 2 and 3 SMA, and overall, "there is an extremely limited database," said the Council, noting that only 10 patients out of 50 were followed up with after approximately five years
- Danish drug purchaser AMGROS and Novartis will negotiate a price for Zolgensma, which the Council will consider when determining whether to recommend Zolgensma for standard treatment at the end of May

THE DETAILS

COPENHAGEN, Denmark – The Danish Medicines Council has concluded that Novartis' Zolgensma (onasemnogene abeparvovec) works just as well as Biogen's Spinraza (nusinersen) in infants with spinal muscular atrophy (SMA) and has requested that Novartis provide further documentation of the gene therapy's efficacy and set a price that considers the uncertainty about its effect.

Jorgen Scholer Kirstensen of the Medical Council explained, "The two treatments seem to have roughly equal effect for patients. The advantage of the new gene therapy is that the patient only has to have a single injection, while Spinraza has to be injected into the cavity that surrounded the spinal cord, every four months for the rest of their life. However, the one-time treatment can also be a disadvantage for the patient if there subsequently turns out to be unknown side effects."

The Council's review of Zolgensma is based on studies involving infants with Type 1 SMA who were under six months of age when they received treatment and infants who were born with SMA but hadn't yet expressed symptoms. In these patients, Zolgensma was found to work equally as well as Spinraza.

However, there are no studies on Zolgensma in older children or those with Types 2 and 3 SMA; overall, "there is an extremely limited database," said the Council, noting that only 10 patients out of 50 were followed up with after approximately five years.

The Council wants additional follow up and more documentation on the effect of Zolgensma, including on reported serious side effects (thrombotic microangiopathy) five patients out of 800 treated with the gene therapy experienced.

Danish drug purchaser AMGROS and Novartis will negotiate a price for Zolgensma, and based on this price, the Council will determine at the end of May whether to recommend Zolgensma for standard treatment. Nevertheless, the Council has opined that its doubts regarding the long-term efficacy of the gene therapy "must be reflected in the price," said Council Chair Steen Werner Hansen.

Germany to Make E-Prescription App Available from July

Date: May 24, 2021 | Country: GERMANY | Region: EUROPE | Type: Policy | Keywords: #digitalization #electronic #eprescription #germant #jensspahn #pharmacy

PRICENTRIC BRIEF:

- Germany has announced plans to make its e-prescription app capabilities live from July 2021, in time for the implementation of mandatory e-prescription use
- German Minister of Health Jens Spahn announced earlier this year that the federal government aims to require all prescriptions be issued in electronic form from January 1, 2022, with some exceptions
- Originally submitted by the Federal Ministry of Health (BMG) at the end of January this year, the PDSG is meant to digitize the health care system and oblige the now nationalized Gematik to create a standard mobile phone app for transmitting prescriptions, with the capability of forwarding them on to the applications of other providers like on-site pharmacies and mail order companies

THE DETAILS

COPENHAGEN, Denmark – The Danish Medicines Council has concluded that Novartis' Zolgensma (onasemnogene abeparvovec) works just as well as BERLIN, Germany – Germany has announced plans to make its e-prescription app capabilities live from July 2021, in time for the implementation of mandatory e-prescription use.

Under the new system, a prescription code is generated that a patient's doctor can then transmit to the patient's e-prescription app. To redeem the e-prescription, a patient must open the prescription code in the app and show it to the pharmacy or the prescription can be sent to a pharmacy in advance. Alternatively, the recipe code can also be issued in paper form.

However, German Minister of Health Jens Spahn announced earlier this year that the federal government aims to require all prescriptions be issued in electronic form from January 1, 2022, with some exceptions. The newly added regulation requiring e-prescriptions was a surprise when it was announced, since Spahn and his ministry previously said the paper prescription should be preserved.

Originally submitted by the Federal Ministry of Health (BMG) at the end of January this year, the Patient Data Protection Act (PDPA) is meant to digitize the health care system and oblige the now nationalized Gematik to create a standard mobile phone app for transmitting prescriptions, with the capability of forwarding them on to the applications of other providers like on-site pharmacies and mail order companies.

Gematik Expansion

Germany's umbrella payer GKV-Spitzenverband (GKV-SV) previously explained in a release that the expansion of the society for telematics applications of healthcare, also known as Gematik, is "particularly problematic'" given that its actions are "increasingly no longer limited to organizational and systemic aspects of the digitization of the health system."

"Gematik creates more and more direct interfaces and access to the insured and can thus directly influence the way in which the insured experience the digitalization of the health system, understand their health, which paths are followed and products are used. This enables them to bypass key players such as doctors and health insurance companies," according to Dr. Doris Pfeiffer, Chairwoman of the board of the National Association of Statutory Health Insurance Funds.

In April, GKV-SV also expressed concern that despite health insurance companies offering a technical process with which the insured can access an e-prescription, its implementation is optimistic in terms of timing.

Dr. Pfeiffer noted: "The necessary - and legally stipulated - specifications of Gematik do not exist at all, so far Gematik has not even received an order for their creation."

CHMP Recommends 8 Medicines for Approval, Including bluebird's New Gene Therapy

Date: May 24, 2021 | Country: NETHERLANDS | Region: EU27, EUROPE | Type: HTA | Keywords: #albiero #almirall #amgen #astrazeneca #bayer #bioprojet #bluebird #bms #boehringeringelheim #chmp #codon #covid19 #ema #gedeonrichter #generic #gilead #indicationexpansion #janssen #msd #novartis #ozawade #raredisease #regeneron #rhythm #roche #ryego #skysona #vaccine #cellandgenetherapy

PRICENTRIC BRIEF:

- During its May meeting, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended eight medicines for approval, including one new gene therapy, bringing its yearly total to date to 42 positive opinions
- CHMP recommended granting marketing authorization to bluebird bio's gene therapy Skysona (elivaldogene autotemcel) for the treatment of early cerebral adrenoleukodystrophy (CALD) in patients without a matched sibling hematopoietic stem cell donor, based on an assessment by EMA's Committee for Advanced Therapies (CAT)
- CHMP also issued seventeen recommendations on extensions of therapeutic indication, including for Amgen's Blincyto (blinatumomab), BMS' Evotaz (atazanavir/cobicistat), Opdivo (nivolumab), and Yervoy (ipilimumab); Novartis' Eucreas (vildagliptin/metformin hydrochloride), Galvus (vildagliptin), Icandra (vildagliptin/metformin hydrochloride), Jalra (vildagliptin), Xiliarx (vildagliptin), and Zomarist (vildagliptin/metformin hydrochloride); Boehringer Ingelheim's Jardiance (empagliflozin); MSD' Keytruda (pembrolizumab); and CO.DON AG's Spherox (spheroids of human autologous matrix-associated chondrocytes), as well as two extensions for Regeneron's Libtayo (cemiplimab) and Janssen's Darzalex (daratumumab)

THE DETAILS

AMSTERDAM, Netherlands – During its May meeting, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended eight medicines for approval, including one new gene therapy, bringing its yearly total to date to 42 positive opinions.

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The Committee adopted a positive opinion, recommending granting marketing authorization under exceptional circumstances for Albiero's Bylvay (odevixibat) for the treatment of progressive familiar intrahepatic cholestasis (PFIC) in patients aged six months and up.

CHMP also issued positive opinions for Rhythm's Imcivree (setmelanotide) for the treatment of obesity and the control of hunger associated with genetic deficiencies of the melanocortin 4 receptor (MC4R) pathway, Almirall's Klisyri (tirbanibulin mesylate) for the field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis, BIOPROJET's Ozawade for the treatment of excessive daytime sleepiness in obstructive sleep apnea, Gedeon Richter's Ryeqo (relugolix/estradiol/norethisterone acetate) for the treatment of symptoms of uterine fibroids in adult women of reproductive age, and Bayer's Verquvo (vericiguat) for the treatment of chronic heart failure in adult patients with reduced ejection fraction.

In the realm of generics, Accord's icatibant was recommended to receive marketing authorization for the treatment of acute attacks of hereditary angioedema.

CHMP also issued seventeen recommendations on extensions of therapeutic indication, including for Amgen's Blincyto (blinatumomab), BMS' Evotaz (atazanavir/cobicistat), Opdivo (nivolumab), and Yervoy (ipilimumab); Novartis' Eucreas (vildagliptin/metformin hydrochloride), Galvus (vildagliptin), Icandra (vildagliptin/metformin hydrochloride), Jalra (vildagliptin), Xiliarx (vildagliptin), and Zomarist (vildagliptin/metformin hydrochloride); Boehringer Ingelheim's Jardiance (empagliflozin); MSD' Keytruda (pembrolizumab); and CO.DON AG's Spherox (spheroids of human autologous matrix-associated chondrocytes), as well as two extensions for Regeneron's Libtayo (cemiplimab) and Janssen's Darzalex (daratumumab).

Amidst the ongoing COVID-19 Pandemic, the Committee provided additional advice on blood clots or low blood platelets occurring after vaccination with AstraZeneca's COVID-19 vaccine Vaxzevria, and recommended renewed conditional marketing authorization for Gilead's COVID-19 antiviral, Veklury (remdesivir), for patients aged 12 years and up with COVID-19-associated pneumonia who require supplemental oxygen.

Finally, CHMP confirmed its previous recommendation to use Roche's Tecentriq (atezolizumab) only in combination with nab-paclitaxel and not with conventional paclitaxel when treating patients with locally advanced or metastatic triple-negative breast cancer (TNBC) that cannot be surgically removed.

China Allows Retail Pharmacies to Supply NRDL Drugs Under "Dual-Channel" Initiative

Date: May 11, 2021 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: | Keywords: #availability #basicmedicalinsurance #compensation #dualchannel #hospital #nhsa #nrdl #pharmacy

PRICENTRIC BRIEF:

- Through "Guidance Opinions for Establishing and Improving the 'Dual-Channel' Management Mechanism of Negotiated NRDL Drug Products," Chinese authorities are allowing a second channel, retail pharmacies, to supply National Reimbursement Drug List (NRDL) drugs, expanding the previous scope of suppliers of these drugs from just hospitals

- Which drugs can be supplied by designated pharmacies is up to the discretion of provincial medical insurance administration departments, with consideration for the province's level of economic development, basic medical insurance (BMI) fund affordability, and patient need—However, drugs with high clinical value, urgent patient need, and low substitution should be available through this second channel

- Pharmacies need to be interfaced with the medical insurance information and electronic prescription platforms, and dual channel availability of NRDL drugs also requires unified, standardized payment policies for retail pharmacies and medical institutions (primarily hospitals)

THE DETAILS

BEIJING, China – Through "Guidance Opinions for Establishing and Improving the 'Dual-Channel' Management Mechanism of Negotiated NRDL Drug Products," Chinese authorities are allowing a second channel, retail pharmacies, to supply National Reimbursement Drug List (NRDL) drugs, expanding the previous scope of suppliers of these drugs from just hospitals.

The document highlights seven guiding principles for the implementation of a "dual channel" that call for classifying NRDL drugs by high clinical value, demand, and costs, screening retail pharmacies to make sure they can supply these products, and improving payments and reimbursement for these drugs.

Which drugs can be supplied by designated pharmacies is up to the discretion of provincial medical insurance administration departments, with consideration for the province's level of economic development, basic medical insurance (BMI) fund affordability, and patient need. However, drugs with high clinical value, urgent patient need, and low substitution should be available through this second channel.

Pharmacies serving the dual-channel initiative must be interfaced with the medical insurance information and electronic prescription platforms, and be well-versed in drug management, such as storage, distribution, and safety, while remaining respectful of drug rationing.

Dual channel availability of NRDL drugs also requires unified, standardized payment policies for retail pharmacies and medical institutions (primarily hospitals), while simultaneously strengthening BMI fund management and optimizing relevant services, such as settlement.

Recently, China's National Healthcare Security Administration (NHSA) announced that 19 drugs newly included in the 2020 National Reimbursement Drug List (NRDL) were now available in 3,324 designated medical institutions, with 15 of these drugs available in 20 provinces. In December 2020, China concluded negotiations for new drug entries onto the NRDL, adding 119 drugs covering 31 therapeutic areas at price reductions of, on average, 51%. In total, the 2020 NRDL ended up with 2,800 products, of which 1,426 were western medicines and 1,374 proprietary Chinese medicines.

China's 5th Round of VBP Officially Covers 60 Drugs, 202 Specifications, Says Joint Procurement Office Notice

Date: May 11, 2021 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: Editor's Choice, Tender | Keywords: #bidding #centralizedprocurement #chinamarketeddrugformulary #generic #gqce #jointprocurementoffice #pricingandreimbursement #volumebasedprocurement

PRICENTRIC BRIEF:

- The Joint Procurement Office (JPO) has released a notice that it is currently collecting relevant drug information, including on companies and their certifications, for China's fifth round of volume-based procurement, which according to the announcement will cover 60 drugs for 202 product specifications
- Products that are eligible to participate in the 5th round of VBP must be domestically-marketed drugs with valid approval documentation, and are originator drugs or reference formulations that passed generic quality and clinical evaluation (GQCE), drugs that passed GQCE, generics approved under the new chemical registration classification, or drug products list on the China Marketed Drug Formulary
- The drugs up for grabs in round five include, in varying formulations: Omega-3 fish oil, Alfacalcidol, Aripiprazole, Esomeprazole, Olopatadine, Oxaliplatin, Benazepril, Bepotastine, Cisatracurium besylate, Bicalutamide, Dabigatran etexilate, Isosorbide mononitrate, Decitabine, Iohexol, Iodixanol, Dutasteride, Docetaxel, Fasudil, Glipizide, Glycopyrrate, Ganciclovir, Potassium sodium hydrogen citrate, Gemcitabine, Carbetocin, Lansoprazole, Lercanidipine, Rivaroxaban, Lipoic acid, Ropivacaine, Potassium chloride, Metoprolol, Mifepristone, Miglitol, Misoprostol, Palonosetron, Propranolol, Saxagliptin, Venlafaxine, Cinacalcet, Thymalfasin, Promethazine, Ipratropium bromide, Fat emulsion amino acid, Medium/long-chain fat emulsion, Bendamustine hydrochloride, Paclitaxel, Azithromycin, Budesonide, Fluconazole, Linezolid, Moxifloxacin, Tinidazole, Cefuroxime, Ceftriaxone, Cefazolin, and Levofloxacin sodium

THE DETAILS

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At the beginning of 2021, China's General Office of the State Council formally issued "Opinions on Promoting the Normalized and Institutionalized Development of Centralized and Volume Procurement of Drugs," thereby officially announcing the normalization and institutionalization arrangements for centralized drug procurement.

According to Premier Li Keqiang, "The bulk-buying program has worked well," said Li. "It is a major step in reforming medical institutions. The scheme has helped to lower, over time, medical costs for the public, and keep the operation of medical insurance funds sustainable."

China's national, centralized procurement has expanded significantly since its pilot known as the "4+7 tender trial" launched in 11 select cities in 2018. On average, China has secured medicines through VBP at price cuts of 53%-54%. At the start of February, China's fourth round of VBP commenced, seeking 45 drugs across a variety of therapeutic areas including hypertension, diabetes, gastrointestinal diseases, mental illnesses, and malignant tumors.

Going forward, VBP could take place twice a year, and the initiative will expand to cover all types of clinically necessary drugs, including Chinese-patented medicines and biosimilars. At a January meeting during which Chinese officials laid out the trajectory of the initiative, it was agreed that 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 in 2022.

China Starts Roll Out of Urgently Needed, Newly Listed NRDL Drugs

Date: May 10, 2021 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: Pricing & Reimbursement | Keywords: #nhsa #nrdl

PRICENTRIC BRIEF:

- China's National Healthcare Security Administration (NHSA) has announced that 19 drugs newly included in the 2020 National Reimbursement Drug List (NRDL) are now available in 3,324 designated medical institutions, with 15 of these drugs available in 20 provinces
- In December 2020, China concluded negotiations for new drug entries onto the NRDL, adding 119 drugs covering 31 therapeutic areas at price reductions of, on average, 51%
- The following drugs were made available due to urgent clinical need and few alternatives being available: Zejula (niraparib), Baizean (tislelizumab), Tuoyi (toripalimab), camrelizumab, Almonertinib, Prolia/Xgeva (denosumab), inetetamab, Brukinsa (zanubritinib), Xtandi (enzalutamide), Mekinist (trametinib), Tafinlar (dabrafenib), Lenvima (lenvatinib), flumatinib, Ofev (Nintedanib), Austedo (eutetrabenazine), Radivaca (Edaravone), coblopasvir, Benlysta (belimumab), and Dupixent (dupilumab)

THE DETAILS

BEIJING, China – China's National Healthcare Security Administration (NHSA) has announced that 19 drugs newly included in the 2020 National Reimbursement Drug List (NRDL) are now available in 3,324 designated medical institutions, with 15 of these drugs available in 20 provinces.

In December 2020, China concluded negotiations for new drug entries onto the NRDL, adding 119 drugs covering 31 therapeutic areas at price reductions of, on average, 51%. Homegrown PD-(L)1 inhibitors secured spots on the listing, beating out those from overseas drugmakers. In total, the 2020 NRDL ended up with 2,800 products, of which 1,426 were western medicines and 1,374 proprietary Chinese medicines.

The following drugs were made available due to urgent clinical need and few alternatives being available:

- Zejula (niraparib)
- Baizean (tislelizumab)
- Tuoyi (toripalimab)
- Camrelizumab
- Almonertinib
- Prolia/Xgeva (denosumab)
- Inetetamab
- Brukinsa (zanubritinib)
- Xtandi (enzalutamide)
- Mekinist (trametinib)
- Tafinlar (dabrafenib)
- Lenvima (lenvatinib)
- Flumatinib
- Ofev (Nintedanib)
- Austedo (eutetrabenazine)
- Radivaca (Edaravone)
- Coblopasvir
- Benlysta (belimumab)
- Dupixent (dupilumab)

China Approves Henan Cross-Border Retail E-Commerce Pilot of Imported OTC Drugs

Date: May 18, 2021 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: Regulation | Keywords: #ecommerce #import #nmpa #otc #pilot

PRICENTRIC BRIEF:

- China's State Council has approved a three-year cross-border e-commerce retail drug pilot for Henan Province that will cover 13 non-prescription (over the counter; OTC) drugs
- Formulated by the General Administration of Customs, State Administration of Taxation, State Administration of Market Supervision, and National Medical Products Administration (NMPA), the catalogue of 13 drugs will not be expanded during the trial period
- The tariff rate for these 13 OTC medicines will temporarily be 0% and value-added tax (VAT) and consumption tax will temporarily be levied at 70%

THE DETAILS

ZHENGZHOU, China – China's State Council has approved a three-year cross-border e-commerce retail drug pilot for Henan Province that will cover 13 non-prescription (over the counter; OTC) drugs.

Formulated by the General Administration of Customs, State Administration of Taxation, State Administration of Market Supervision, and National Medical Products Administration (NMPA), the catalogue of 13 drugs will not be expanded during the trial period.

The tariff rate for these 13 OTC medicines will temporarily be 0% and value-added tax (VAT) and consumption tax will temporarily be levied at 70%.

Henan's provincial government has been advised by the State Council to supervise the situation to ensure the quality and safety of these OTC drugs.

Russia's Patient Union Wants Auctions for High-Cost Nosologies Replaced with Direct Purchases

Date: May 3, 2021 | Country: RUSSIA | Region: ASIA & SOUTH PACIFIC, EUROPE | Type: Tender | Keywords: #auction #directpurchase #fas #highcostnosology #procurement #vsp #vzn

PRICENTRIC BRIEF:

- The All-Russian Union of Patients (VSP) has written to the Russian Government and Ministry of Health requesting changes to the drug procurement mechanism for centralized procurement of high-cost nosologies (VZN) in order to expedite access to treatment for patients in need
- For VSP, the Ministry of Health should nix auctioning and instead allow direct purchases, specifically in instances of "unique products," as there is no need for an auction when there is no competition—According to VSP Co-Chairman Yuri Zhulev, "There is no competition in this segment among manufacturers, there are no analogues, from year to year the same companies go to the auction, without ever changing the cost of their drug"
- When additional drugs are required due to there being more eligible patients identified, these treatments should be purchased within the framework of existing contracts, and the time for which it takes to agree and conclude a contract should be reduced to just three working days, argued VSP, and there is no need for approval from the Federal Antimonopoly Service (FAS), particularly when there is only one competitor bidding in the auction

THE DETAILS

MOSCOW, Russia – The All-Russian Union of Patients (VSP) has written to the Russian Government and Ministry of Health requesting changes to the drug procurement mechanism for centralized procurement of high-cost nosologies (VZN) in order to expedite access to treatment for patients in need.

As it stands, VZN products are procured through auctioning, even when certain medicines have no competition (they are "unique products"), a process that, from start to finish, takes around one and a half months. Timeliness is a concern for VSP, especially when it comes

to the process for drawing up patient lists: Russia's regions complete patient lists in October/November, and patients who don't make the list have to wait until next year. Granted, companies offer treatments through compassionate use, however, the duration of their offering is only typically a few months.

Last year's VZN purchases are not enough. The supply was intended to last 15 months, but there is only one year's worth of product, and patients with multiple sclerosis (MS), hemophilia, Gaucher disease, and cystic fibrosis (CF) were the most impacted.

Overall, the process is too bureaucratic for VSP, which has scrutinized the lengthiness of concluding contracts as well as the way in which Russia handles procuring medicines included in the VZN program.

For VSP, the Ministry of Health should nix auctioning and instead allow direct purchases, specifically in instances of "unique products," as there is no need for an auction when there is no competition. According to VSP Co-Chairman Yuri Zhulev, "There is no competition in this segment among manufacturers, there are no analogues, from year to year the same companies go to the auction, without ever changing the cost of their drug."

When additional drugs are required due to there being more eligible patients identified, these treatments should be purchased within the framework of existing contracts. Moreover, the time for which it takes to agree and conclude a contract should be reduced to just three working days, argued VSP, and there is no need for approval from the Federal Antimonopoly Service (FAS), particularly when there is only one competitor bidding in the auction.

Pakistan's DRAP Tells Doctors to Prescribe by Generic Name

Date: May 6, 2021 | Country: PAKISTAN | Region: ASIA & SOUTH PACIFIC | Type: Policy | Keywords: #branddrug #drap #generic #pma #prescribingguidelines #prescription

PRICENTRIC BRIEF:

- The Drug Regulatory Authority of Pakistan (DRAP) has requested doctors across the provinces to prescribe medicines by generic name after receiving public complaints through the Prime Minister's Performance Delivery Unit (PMDU) that the pharmaceutical industry and doctors colluded to make patients choose costlier medicines
- The move seeks to promote generic prescriptions and discourage incentivized prescribing
- Whereas pharmacists have backed the measure, as it could relieve the financial burden on patients, Pakistan's medical association is against any mandate, instead wanting the generics drug policy to be rectified and for better, standardized pricing for generics

THE DETAILS

ISLAMABAD, Pakistan – The Drug Regulatory Authority of Pakistan (DRAP) has requested doctors across the provinces to prescribe medicines by generic name after receiving public complaints through the Prime Minister's Performance Delivery Unit (PMDU) that the pharmaceutical industry and doctors colluded to make patients choose costlier medicines.

The move seeks to promote generic prescriptions and discourage incentivized prescribing.

The Reformers Pharmacist Pakistan has backed DRAP's mandate to prescribe by generic name, mainly to lessen the financial burden on patients, but also demanded that pharmacies have a qualified pharmacist on premise to help distinguish between brand and generic drugs.

On the other hand, the Pakistan Medical Association (PMA) is against the measure, claiming it to be an overreach as the agency should've first consulted stakeholders before determining prescribing by generic name.

Before enforcing this type of prescribing, PMA has urged DRAP to rectify failed generic drug policies and make sure all generic drugs of the same name, regardless of manufacturer, cost the same.

Dubai's Essential Benefits Plan Offers Fewer Branded Medicines to Basic Plan-holders

Date: May 7, 2021 | Country: UNITED ARAB EMIRATES | Region: MIDDLE EAST | Type: Policy | Keywords: #branddrug #drugformulary #dubaiessentialplan #dubaihealthauthority #generic #isahd #outofpocket #shifa

PRICENTRIC BRIEF:

- Several branded medicines previously a part of Dubai's Essential Benefits Plan were removed in mid-February with the roll-out of Dubai's new, unified formulary (SHIFA), meaning beneficiaries of the AED 600 basic health insurance plan will have to pay out of pocket for medicines not on the formulary
- Having taken effect February 18, 2021, SHIFA replaced the formularies of each hospital and health insurance plan under Dubai Health Authority's (DHA) Insurance System for Advancing Healthcare in Dubai (ISAHD), an initiative seeking to provide healthcare for Dubai residents, nationals, and visitors
- As reported by Gulf News, Dubai's formulary was slimmed down to around 700 generic medicines from 2,500, as SHIFA seeks to promote access to a unified set of medicines; ergo, any Dubaians in need of medicines not listed on the formulary must either purchase them on their own or upgrade their policy

THE DETAILS

DUBAI, United Arab Emirates – Several branded medicines previously a part of Dubai's Essential Benefits Plan were removed in mid-February with the roll-out of Dubai's new, unified formulary (SHIFA), meaning beneficiaries of the AED 600 basic health insurance plan will have to pay out of pocket for medicines not on the formulary.

Under Dubai's health insurance revamp, only those products listed on SHIFA can be used by Essential Benefit Plan beneficiaries. Any Dubaians in need of medicines not listed on the formulary must either purchase them on their own or upgrade their policy—which according to Vikas Katoch, Chief Operating Officer of healthcare operator Right Health, could cost another AED 800-1,500 per year.

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According to its website, ISAHD has two main pillars: provide insurance coverage for everyone in Dubai and monitor and introduce enhancements towards sustainable high-quality healthcare system. Echoing the core aims of ISAHD, the unified formulary is comprised of commercially available and licensed outpatient drugs, including innovative drugs, to ensure unified access to the most effective treatments.

King Saud University Establishes HTA Unit for Saudi Arabia

Date: May 26, 2021 | Country: SAUDI ARABIA | Region: MIDDLE EAST | Type: Breaking News, HTA | Keywords: #arabia #assessment #health #hta #pricing #riyadh #saudi #technology

PRICENTRIC BRIEF:

- Hussain Al-Omar, Associate Professor of Pharmacoeconomics at King Saud University has announced the formation of a new Health Technology Assessment (HTA) Unit for Saudi Arabia
- The organization is the first unit of its kind to be launched in the region and is being implemented in order to "serve the needs of health policy and decision-makers in both public and private sectors whilst keeping them informed using a scientific approach and robust methods"
- When announcing the unit, Al-Omar noted: "Globally, entities are leaning towards a more sustainable future with value-based approaches to help reduce unwarranted spending. As such, the HTA Unit will take part in advising our partners about mechanisms of pharmaceutical pricing and reimbursement for novel health technologies as well as propose the best innovative payment models"

THE DETAILS

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"Additionally, the unit will provide reinforcements in the form of health economic models, budget impact models, HTA and health economics training and building capabilities in the country. By doing so, the unit will be working in tandem with governmental and private bodies; providing support and meeting the objectives of the Kingdom's 2030 vision."

Following the announcement, Pricentric is keeping track of updates in real-time and will update the newsfeed as more information becomes available.

The announcement follows speculation of developing HTA practices in the region.

Speaking at the recent EPA World Congress, Mostafa Alabed, Ministry of Health Saudi Arabia explained how the country is divided into two sections, public and private healthcare systems.

The largest healthcare provider is the Ministry of Health, which provides 60% of healthcare, followed by other government ministries which provide approximately 20% for employees and their families. The final 20% is provided by the private sector.

According to Alabed, Saudi Arabia is currently dealing with a number of challenges:

- Increasing life expectancy
- High chronic diseases rates
- Inadequate primary care
- Gaps in the quality of service provided to patients
- Gaps in workforce capacity and capability
- The upcoming national transformation plan (NTP) hopes to transform healthcare by easing access to health services, improving the quality and efficiency of healthcare services, and promoting prevention against health risks

Pertaining to Al-Omar's new announcement of an HTA agency, Alabed also noted that there are a number of expectations with the establishment of an official HTA body, but workshops are currently occurring that gather experts from different backgrounds to discuss topics and share knowledge that will help guide the project in the right direction.

He also noted how HTA can cause a delay in access if not done properly and as such there should be a national mandate informing decision for the whole population, regardless of cover by the Ministry of Health or not.

Decision-making needs to be "independent and transparent," Alabed noted. "The HTA process should address the full scope of technologies. There has also been a suggestion that medical devices need more medical assessment."

He added, "Establishing an independent HTA center is one of the steps to improve value-based healthcare, it has an important role in healthcare around the world especially when it comes to resource allocation and decision making."

Saudi Arabia is undergoing a number of changes in relation to drug pricing and reimbursement, including the introduction of a new pricing policy, updating guidelines for determining the prices of medicines and reorganizing the Kingdom's reference basket.

These changes took effect on January 14, 2021.

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

Brazil Supreme Court Rules Against Patent Extensions Paving Way for Earlier Generics, Biosimilars

Date: May 20, 2021 | Country: BRAZIL | Region: SOUTH AMERICA | Type: Policy | Keywords: #access #biosimilar #evergreening #generic #ipright #litigation #monopoly #patent #priceincrease #supremecourt

PRICENTRIC BRIEF:

- Brazil's Supreme Court has ruled against the minimum 10-year patent term decreed in Brazil's Intellectual Property Statute, deciding that all patents will be valid for 20 years from the filing date
- The Court ultimately ruled the extension as unconstitutional because it is an automatic extension and not limited enough to prevent evergreening—plus, it has undermined the temporality of patents and led to increased medicine prices in Brazil by creating monopolies and limiting access to pharmaceuticals, said the Court
- Following this ruling, generic drugmakers have filed 46 lawsuits targeting 79 patents, including those for Amgen's Repatha (evolocumab), GlaxoSmithKline's Nucala (mepolizumab), Bayer's Xarelto (rivaroxaban), and Pfizer's Xalkori (crizotinib) and Ibrance (palbociclib), and the retroactive application of the Court's decision could impact 4,000 pharmaceutical patents

THE DETAILS

BRASILIA, Brazil – Brazil's Supreme Court has ruled against the minimum 10-year patent term decreed in Brazil's Intellectual Property Statute, deciding that all patents will be valid for 20 years from the filing date.

In some instances, Brazil took 11 to 20 years to grant patents; ergo, to make up for the pendency period, enacted a minimum 10-year patent term, which the Court ultimately ruled as unconstitutional because it is an automatic extensions and not limited enough to prevent evergreening. For the Court, the 10-year extension undermines the temporality of patents and has led to increased medicine prices in Brazil by creating monopolies and limiting access to pharmaceuticals.

Following this ruling, generic drugmakers have filed 46 lawsuits targeting 79 patents, including those for Amgen's Repatha (evolocumab), GlaxoSmithKline's Nucala (mepolizumab), Bayer's Xarelto (rivaroxaban), and Pfizer's

Xalkori (crizotinib) and Ibrance (palbociclib), among others. The retroactive application of the Court's decision could shorten the patent terms for upwards of 4,000 pharmaceutical patents.

Now, patents will be valid in Brazil for 20 years from filing, no matter how long Brazil's Patent Office (INPI) to grant a patent, and it is expected that the ruling will lead to earlier launches of generics and biosimilars.

ISPOR 2021 Highlights

Pricentric INSIGHTS news team attended the ISPOR 2021 virtual conference, where we listened to presentations on current pharma trends. See below a brief for each presentation.

Are Child QALYs Equivalent to Adult QALYs?

- During the virtual broadcast of ISPOR 2021, panelists discussed whether child QALYs should differ from adult QALYs which would have implications for the evaluation of technologies that cover both children and adults, and for clinical trials in which participants are children at baseline and transition to adulthood by the end of the trial
- Nancy Devlin, PhD, University of Melbourne, noted the child QALY issue is important to discuss because "decisions to spend more on a new technology to improve health in adults has an opportunity cost in child health, and vice versa" and a gap in evidence related to pediatric QALYs creates the potential for significant misallocation of funds
- Age neutrality in Health Related Quality of Life (HRQoL) utilities, Devlin said, could be achieved to cater to decision contexts by minimizing differences between valuation methods of adults and children, mapping from child HRQoL instruments to adult HRQoL instruments, and developing tasks to "empirically identify the underlying latent 'willingness to trade'"Now, patents will be valid in Brazil for 20 years from filing, no matter how long Brazil's Patent Office (INPI) to grant a patent, and it is expected that the ruling will lead to earlier launches of generics and biosimilars.

Real World Evidence Utilization Challenges

- Publication bias, generalizability, cherry-picking, torture data to confession, and promise/threat of data science are example areas of skepticism, said Laura Happe, PharmD, MPH, Academy of Managed Care Pharmacy, during the virtual broadcast of ISPOR 2021, though the use of RWE will "certainly" become more widely referenced by payers in the future
- Jonathan Kowalski, PharmD, MS, BresMed US, said accelerating interest in RWD is driven by technological innovation enabling advanced analytics, remote data storage and tokenization, and even blockchain
- Kowalski noted that performing a real-world study in the market should be voluntary, along with a way to mask proprietary information until the study is completed

HTA's Evolving Role for More Integrated Latin American Health Systems

- During the virtual broadcast of ISPOR 2021, panelists discussed key areas where HTA is evolving across Latin America's "highly fragmented healthcare landscape," including with high-cost novel therapies and the deployment of HTA in hospitals
- Latin American countries are all in various stages of development when it comes to increasing access to therapies yet they need to align "on some kind of backbone," stressed Stephen Stefani, MD, MBA, UNIMED Central RS, and every stakeholder of the healthcare system has a role to play as opposed to passing on the blame
- An innovative technique with roots in Europe, called Hospital Based Health Technology Assessment (HopHTA), has been introduced in some Mexican hospitals but evidence of the influence of HopHTA is yet to be determined

The Role HTA Should Play in the U.S. Healthcare Marketplace

- During the virtual broadcast of ISPOR 2021, panelists discussed six recommendations by an expert panel sponsored by the USC Schaeffer Center and the Aspen Institute for public funding of an advisory-only HTA in the U.S.
- The group recommended that the U.S. establish a publicly funded HTA coordinating entity—the Institute for Health Technology Assessment (IHTA)—to bolster the HTA landscape and improve decision making in the healthcare marketplace

- Peter J. Neumann, ScD, Tufts Medical Center, said that private HTAs should continue and admits ICER does "some good work", though ICER is "not accountable" and has a strict focus on drugs only (rather than also assessing devices and more broadly defined interventions)

Access to Oncology Combinations

- During the virtual broadcast of ISPOR 2021, Tim Wilsdon, MSc, believes the challenge to reimbursing combination therapies is a structural one—Only one of the manufacturers, the one of the new add-on therapy, is allowed to negotiate on the price, thus there is no way to develop an effective price for the combination therapy as a whole
- Wilsdon suggested combination therapies should be assessed as a single entity versus the standard of care and confidential rebates should be enabled, which differentiate between combination and monotherapy use and use in different combination indications
- A dedicated trading platform should be set up for each constituent to indirectly participate in voluntary negotiations, Wilsdon continued and manufacturers of each constituent should indirectly participate in voluntary negotiations through iterative discussions with payers

Reimbursement Challenges and Pricing Opportunities in the U.S.

- During the virtual broadcast of ISPOR 2021, panelists discussed reimbursement challenges and pricing opportunities in the U.S. including drug value evidence-based issues, coverage policies, value assessment frameworks, contracting and affordability
- Lou Garrison, PhD, University of Washington, said a task force at ISPOR was "agnostic" about whether or not to monetize the value flower or use multi-criteria decision analysis, or do both, though he would argue that the QALY should still be a key attribute with other things added on top
- Further, Garrison said, it is estimated that the economic burden of genetic diseases, according to a 2019 analysis, is about $1 trillion, stating, "We're currently spending $3.8 trillion on healthcare, so the good news is, it's only $1 trillion. Our GDP is like $21 trillion so there's headroom in there"

The Greatest Challenges Now Facing Payers

- During the virtual broadcast of ISPOR 2021, panelists discussed funding and access challenges related to gene therapies coming to market including inequities between private and public healthcare plans, implementation of value-based contracting, and issues with portability between private healthcare plans
- Michael Sherman, MD, MBA, MS, Harvard Pilgrim / Tufts Health Care, brought to everyone's attention that therapies like Zolgensma are approved because they affect a small population so it doesn't "break the bank," but if there is a transformative therapy that impacts many more people, especially if there are already therapies out there that are already safe and effective, policy needs to change to enable access
- Sherman said the first thing needed is a "sophisticated system that takes into account various types of a disease" rather than having a "one number fits all" approach, especially because he expects more drugs to enter the market that benefit various populations differently due to age, disease progression, and other factors

Should U.S. Import Prescription Drugs From Canada?

- During the virtual broadcast of ISPOR 2021, panelists discussed the proposed U.S. drug re-importation plan which is supported by many U.S. payers and patient associations while facing opposition from drug makers and providers
- Andras Incze, PhD, MBA, Baden-Wuerttemberg Cooperative State University Germany, recommended rewarding fulfillment of local demand and discouraging exportation if it leads to a shortage—If appropriate policy and a legal framework is designed, he said, Canada may not need to go to a supply-deep-freeze irrespective of what other countries are legislating
- When the moderator asked the panelists why we shouldn't let the U.S. negotiate with manufacturers as private payers do, Louis P. Garrison, PhD, University of Washington, said, "there is some nervousness about the government having that much power…but it may well be that Medicare negotiation is where we end up"

Advanced Therapies Congress 2021

Pricentric INSIGHTS news team attended the Advanced Therapies Congress 2021 virtual conference, where we listened to presentations on current pharma trends. See below a brief for each presentation.

Tackling Large-scale, Commercial Regulatory

- On the third day of the 2021 Advanced Therapies Congress, reimbursement framework and market access were the focal points of discussion
- In particular, the idea that the same technologies are being used for COVID that would usually be used in advanced therapy medicinal products (ATMPs), and the effects of seeing these technologies ramped up to large scale production, when large scale in terms of ATMPs or rare disease would usually mean just a number of hundreds
- As it stands, there are still huge gaps between the point of approval for a gene therapy and the time it takes to get to a patient. Indications that need gene therapies are often areas of severe unmet need, so it's imperative that these processes are sped up

Outcome-based Agreements

- On the third day of the 2021 Advanced Therapies Congress, a panel on outcomes-based agreements discussed the challenges to payers and manufacturers as new curative but ultra-expensive therapies for rare and ultra-rare diseases emerge from the pipeline
- Payers need sufficient clinical evidence, which is often not available for such small populations, as well as certainty on the durability of the treatment. Financing of these therapies, especially in risk-sharing agreements and payment terms, continues to need discussion and consideration as more gene therapies emerge
- Alexander Natz, Secretary General of the European Confederation of Pharmaceutical Entrepreneurs (Belgium) noted that "So far, we have seen these types of agreements for Kymriah, Yescarta, Zynteglo and Zolgensma. I think for future agreements there are already those types of agreements in place because payers want to see their risk hedged in a way that if certain outcome parameters are not met, there is a payback guarantee, or that certain amounts are not to be paid for the future"

Development and Regulation, From an EU Point of View

- Speaking at the Advanced Therapies Congress 2021, Klaus Cichutek, President of Germany's Paul Ehrlich Institute outlined his European perspective on the development and regulation of advanced therapy medicinal products (ATMPs)
- Highlighting how the majority of products developed made it to the point of licensing from 2016 onwards, he added that there are currently an additional six ATMPs currently under marketing authorization applications (MAA) evaluation with the European Medicines Agency (EMA)
- He noted that from the side of the regulators, "sometimes it's frightening because we have to decide whether the specific CAR-T therapy and the data presented outweigh the product risk. We have to decide whether the toxicities are manageable under real-world conditions. There are also a number of uncertainties pertaining to the nature of non-controlled, single-arm studies with limited patient numbers. Other concerns include patients dropping out between screening, enrolment and treatment, as well as limited follow-up time."

HTAs, Approvals, Launches & Price Changes

HTA Decisions: Germany

- G-BA in Germany has conducted an assessment of Olumiant (Baricitinib; Eli Lilly) for Atopic Dermatitis. Result: For adult patients with moderate to severe atopic dermatitis who are eligible for a continuous systemic therapy is an option, the added benefit of baricitinib compared to the appropriate comparator therapy has not been proven. NO ADDITIONAL BENEFIT OVER COMPARATOR.

HTA Decisions: United Kingdom

- NICE in United Kingdom has conducted an assessment of Vyndaqel (Tafamidis; Pfizer) for Transthyretin Amyloid Cardiomyopathy. Result: Tafamidis is not recommended, within its marketing authorisation, for treating wild-type or hereditary transthyretin amyloidosis with cardiomyopathy (ATTR-CM) in adults. Tafamidis is the first treatment for ATTR-CM that aims to treat the disease. Evidence from clinical trials shows that it reduces deaths and hospitalisation from conditions affecting the heart and blood vessels compared with placebo. But clinical benefit varies across different types and stages of ATTR-CM. Also, the measure used to assess how severe ATTR-CM is has limitations. This makes it difficult to clearly identify who benefits from tafamidis and whether they should continue treatment. The cost-effectiveness estimates are higher than what NICE normally considers an acceptable use of NHS resources. This is because there is not enough evidence that recommending tafamidis would reduce diagnosis delays and uncertainty about how long the treatment works after it is stopped. So, tafamidis is not recommended.
- NICE in United Kingdom has conducted an assessment of Ondexxya (Andexanet Alfa; Alexion Pharma) for Anticoagulation Reversal. Result: Andexanet alfa is recommended as an option for reversing anticoagulation from apixaban or rivaroxaban in adults with life-threatening or uncontrolled bleeding, only if: 1. The bleed is in the gastrointestinal tract, and 2. The company provides andexanet alfa according to the commercial arrangement.

HTA Decisions: France

- HAS/TC in France has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for CII. Result: The actual benefit of CALQUENCE (acalabrutinib) as monotherapy or in combination with obinutuzumab is only important in the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL), in adult patients without a deletion (del) 17p or TP53 mutation and ineligible for full dose fludarabine therapy, or in adult patients with poor prognosis cytogenetic status (17p deletion or TP53 mutation). SMR (IMPORTANT); ASMR V (ABSENCE).
- HAS/TC in France has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for CII. Result: The actual benefit of CALQUENCE (acalabrutinib) as monotherapy or in combination with obinutuzumab is insufficient in other situations to justify coverage by national solidarity. SMR (INSUFFICIENT).
- HAS/TC in France has conducted an assessment of Kyprolis (Carfilzomib; Amgen) for Multiple Myeloma. Result: The actual benefit of KYPROLIS is substantial in the indication "in combination with daratumumab and dexamethasone in the treatment of multiple myeloma in adult patients who have received at least one previous treatment. SMR (IMPORTANT); ASMR V (ABSENCE).
- HAS/TC in France has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for CII. Result: The actual benefit of CALQUENCE (acalabrutinib) as monotherapy or in combination with obinutuzumab is only important in the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL), in adult patients without a deletion (del) 17p or TP53 mutation and ineligible for full dose fludarabine therapy, or in adult patients with poor prognosis cytogenetic status (17p deletion or TP53 mutation). SMR (IMPORTANT); ASMR V (ABSENCE).
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- HAS/TC in France has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for CII. Result: The actual benefit of CALQUENCE (acalabrutinib) as monotherapy is only important for the treatment of adult patients with CLL who have received at least one previous treatment and who do not have a 17p deletion or a TP53 mutation. SMR (IMPORTANT); ASMR V (ABSENCE).
- HAS/TC in France has conducted an assessment of Isturisa (Osilodrostat; Recordati) for Cushing's Syndrome. Result: The actual benefit of ISTURISA (osilodrostat) is significant in the indication of the marketing authorization. SMR (IMPORTANT); ASMR IV (MINOR).
- HAS/TC in France has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for CII. Result: The actual benefit of CALQUENCE (acalabrutinib) as monotherapy or in combination with obinutuzumab is only important in the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL), in adult patients without a deletion (del) 17p or TP53 mutation and ineligible for full dose fludarabine therapy, or in adult patients with poor prognosis cytogenetic status (17p deletion or TP53 mutation). SMR (IMPORTANT); ASMR V (ABSENCE).
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HTA Decisions: France (cont.)

- HAS/TC in France has conducted an assessment of Adakveo (Crizanlizumab; Novartis) for Vaso-occlusive Crisis (sickle Cell Anemia). Result: The actual benefit of ADAKVEO (crizanlizumab) is low in the indication of the marketing authorization. SMR (LOW); ASMR V (ABSENCE).
- HAS/TC in France has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for CII (obinutuzumab). Result: The actual benefit of CALQUENCE (acalabrutinib) as monotherapy or in combination with obinutuzumab is only important in the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL), in adult patients without a deletion (del) 17p or TP53 mutation and ineligible for full dose fludarabine therapy, or in adult patients with poor prognosis cytogenetic status (17p deletion or TP53 mutation). SMR (IMPORTANT); ASMR V (ABSENCE).
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Drug Approvals: Europe

- YERVOY (IPILIMUMAB) was approved by the EMA for the treatment of adult patients with mismatch repair deficient or microsatellite instability high metastatic colorectal cancer after prior fluoropyrimidine based combination chemotherapy.
COMPANY: BRISTOL-MYERS SQUIBB

- LIBTAYO (CEMIPLIMAB) was approved by the EMA for the treatment of adult patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have progressed on or are intolerant to a hedgehog pathway inhibitor (HHI); and for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations, who have: 1. locally advanced NSCLC who are not candidates for definitive chemoradiation, or 2. metastatic NSCLC.
COMPANY: REGENERON

- OPDIVO (NIVOLUMAB) was approved by the EMA for the treatment of adult patients with mismatch repair deficient or microsatellite instability high metastatic colorectal cancer after prior fluoropyrimidine based combination chemotherapy.
COMPANY: BRISTOL-MYERS SQUIBB

- KEYTRUDA (PEMBROLIZUMAB) was approved by the EMA for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the oesophagus or HER-2 negative gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 10.
COMPANY: MERCK

- JARDIANCE (EMPAGLIFLOZIN) was approved by the EMA for the treatment of symptomatic chronic heart failure with reduced ejection fraction.
COMPANY: BOEHRINGER INGELHEIM

- DARZALEX (DARATUMUMAB) was approved by the EMA in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor and lenalidomide and were lenalidomide-refractory, or who have received at least two prior therapies that included lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or after the last therapy.
COMPANY: JANSSEN-CILAG INTERNAITONAL

- ICATIBANT ACCORD (ICATIBANT) was approved by the EMA for the treatment of acute attacks of hereditary angioedema.
COMPANY: ACCORD

- RYEQO (RELUGOLIX, ESTRADIOL & NORETHISTERONE ACETATE) was approved by the EMA for the treatment of symptoms of uterine fibroids.
COMPANY: GEDEON RICHTER PLC.

- OZAWADE (PITOLISANT) was approved by the EMA for the treatment of excessive daytime sleepiness in obstructive sleep apnoea.
COMPANY: BIOPROJET PHARMA

- IMCIVREE (SETMELANOTIDE) was approved by the EMA for the treatment of obesity and the control of hunger associated with genetic deficiencies of the melanocortin 4 receptor (MC4R) pathway.
COMPANY: RHYTHM

Drug Approvals: Europe (cont.)

- VERQUVO (VERICIGUAT) was approved by the EMA for the treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction.
  COMPANY: BAYER
- KLISYRI (TIRBANIBULIN MESILATE) was approved by the EMA for the treatment of actinic keratosis.
  COMPANY: ALMIRALL
- BYLVAY (ODEVIXIBAT) was approved by the EMA for the treatment of progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older.
  COMPANY: ALBIREO
- SKYSONA (ELIVALDOGENE AUTOTEMCEL)
  was approved by the EMA for the treatment of early cerebral adrenoleukodystrophy (CALD).
  COMPANY: BLUEBIRD BIO

Drug Approvals: United States

- KEYTRUDA (PEMBROLIZUMAB) was approved by the FDA for the first-line treatment of patients with locally advanced unresectable or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma.
  COMPANY: MERCK
- ZYNRELEF (BUPIVACAINE AND MELOXICAM) was approved by the FDA in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty.
  COMPANY: HERON THERAPEUTICS
- EMPAVELI (PEGCETACOPLAN) was approved by the FDA for treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).
  COMPANY: APELLIS
- LEVOTHYROXINE SODIUM (LEVOTHYROXINE SODIUM) was approved by the FDA for the treatment of myxedema coma.
  COMPANY: CUSTOPHARM INC
- OPDIVO (NIVOLUMAB) was approved by the FDA for patients with completely resected esophageal or gastroesophageal junction (GEJ) cancer with residual pathologic disease who have received neoadjuvant chemoradiotherapy.
  COMPANY: BRISTOL-MYERS SQUIBB
- RYBREVANT (AMIVANTAMAB-VMJW) was approved by the FDA for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.
  COMPANY: JANSSEN BIOTECH

Germany: Post-AMNOG Price Changes for Originator Drugs

Company	Product Group	Generic Name	Description	Start Date	MNF	OLD MNF PRICE	MNF AMOUNT CHANGE	MNF PERCENT CHANGE
JANSSEN	ERLEADA	APALUTAMIDE	ERLEADA TABLETS 1 PACK 112 TABS 60 MG	05/01/21	2263.01	2437.08	-174.07	-7.14%
UCB	EVENITY	ROMOSOZUMAB	EVENITY INJECTION 2 PREFILLED PEN 1.17 ML 105 MG	05/15/21	510.89	745.56	-234.67	-31.48%
SANOFI	JEVTANA	CABAZITAXEL	JEVTANA INFUSION 1 VIAL 1.5 ML 60 MG	05/15/21	3100.00	3187.50	-87.50	-2.75%
HORMOSAN	NAMUSCLA	MEXILETINE	NAMUSCLA CAPSULES 1 PACK 100 CAPS 167 MG	05/15/21	1687.25	2300.31	-613.06	-26.65%
HORMOSAN	NAMUSCLA	MEXILETINE	NAMUSCLA CAPSULES 1 PACK 30 CAPS 167 MG	05/15/21	506.17	690.09	-183.92	-26.65%
BIAL	ONGENTYS	OPICAPONE	ONGENTYS CAPSULES 1 PACK 30 CAPS 50 MG	05/01/21	63.75	82.05	-18.30	-22.30%
BIAL	ONGENTYS	OPICAPONE	ONGENTYS CAPSULES 1 PACK 90 CAPS 50 MG	05/01/21	191.25	246.15	-54.90	-22.30%
HEXAL	RIZMOIC	NALDEMEDINE	RIZMOIC TABLETS 1 PACK 10 TABS 200 MCG	05/15/21	15.00	34.76	-19.76	-56.85%
HEXAL	RIZMOIC	NALDEMEDINE	RIZMOIC TABLETS 1 PACK 100 TABS 200 MCG	05/15/21	150.00	347.18	-197.18	-56.79%
HEXAL	RIZMOIC	NALDEMEDINE	RIZMOIC TABLETS 1 PACK 30 TABS 200 MCG	05/15/21	45.00	104.36	-59.36	-56.88%
INFECTOPHARM	SLENYTO	MELATONIN	SLENYTO EXTENDED RELEASE TABLETS 1 PACK 30 TABS 5 MG	05/15/21	99.99	100.50	-0.51	-0.51%
INFECTOPHARM	SLENYTO	MELATONIN	SLENYTO EXTENDED RELEASE TABLETS 1 PACK 60 TABS 1 MG	05/15/21	39.99	40.20	-0.21	-0.52%
ASTELLAS	XTANDI	ENZALUTAMIDE	XTANDI TABLETS 1 PACK 112 TABS 40 MG	05/15/21	2772.79	2745.34	+27.45	+1.00%
ASTELLAS	XTANDI	ENZALUTAMIDE	XTANDI TABLETS 1 PACK 112 TABS 40 MG	05/15/21	2772.79	2745.34	+27.45	+1.00%

Drug Launches: Europe & U.S.

Country	Generic Name	Product Group	Company	Indication	Therapeutic Areas	Product Approval Date	Start Date (Launch Date)
FRANCE	INDACATEROL & MOMETASONE	ATECTURA BREEZHALER	NOVARTIS	ASTHMA	RESPIRATORY	30/5/2020	06/05/2021
UNITED STATES	PEGCETACOPLAN	EMPAVELI	APELLIS PHARMACEUTICALS	PAROXYSMAL NOCTURNAL HEMOGLOBINURIA	NA	14/05/2021	14/05/2021
UNITED STATES	DOSTARLIMAB	JEMPERLI	GLAXOSMITHKLINE	ENDOMETRIAL CANCER (dMMR)	ONCOLOGY	22/04/2021	03/05/2021
UNITED STATES	DROSPIRENONE & ESTETROL	NEXTSTELLIS	MAYNE	CONTRACEPTION	SEX HORMONES	15/04/2021	01/05/2021
UNITED STATES	VILOXAZINE	QELBREE	SUPERNUS PHARMACEUTICALS	ADHD (PEDIATRIC)	NEUROLOGY	02/04/2021	01/05/2021
UNITED STATES	BUPIVACAINE & MELOXICAM	ZYNRELEF	HERON THERAPEUTICS	PAIN (POSTOPERATIVE)	NEUROLOGY	12/05/2021	12/05/2021
GERMANY	RISDIPLAM	EVRYSDI	ROCHE	SPINAL MUSCULAR ATROPHY	MUSCULOSKELETAL DISORDERS	26/03/2021	01/05/2021
GERMANY	PEMIGATINIB	PEMAZYRE	INCYTE	CHOLANGIOCARCINOMA (FGFR2)	ONCOLOGY	26/03/2021	01/05/2021
GERMANY	CABOTEGRAVIR	VOCABRIA	VIIV HEALTHCARE	HIV	ANTIVIRALS	17/12/2020	01/05/2021

Price Changes: Europe & U.S.

Country	Generic Name	Product Group	Company	Therapeutic Area	Avg. Price Change all SKU	First Pricing date
FRANCE	ALECTINIB	ALECENSA	ROCHE	ONCOLOGY	-3.91%	03/08/2018
FRANCE	TRIPTORELIN	DECAPEPTYL	IPSEN	ONCOLOGY	-5.96%	25/08/2001
FRANCE	TRASTUZUMAB	HERCEPTIN	ROCHE	ONCOLOGY	-30.00%	11/05/2005
FRANCE	PEGFILGRASTIM	NEULASTA	AMGEN	HEMATOLOGY	-10.00%	30/07/2003
SPAIN	ROMIPLOSTIM	NPLATE	AMGEN	BLOOD AND BLOOD FORMING ORGANS	-10.00%	06/04/2015
ITALY	HYDROXYZINE	ATARAX	BB - NCIPD	NEUROLOGY	+3.01%	5/31/2019
UNITED STATES	TAGRAXOFUSP	ELZONRIS	STEMLINE THERAPEUTICS	ONCOLOGY	+4.50%	21/12/2018
UNITED STATES	NABUMETONE	RELAFEN	BLUCREST PHARMA	RHEUMATOLOGY	+9.90%	28/08/2020

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