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Pricentric INSIGHT: The Knock-on Effect of Biogen's Aducanumab Approval

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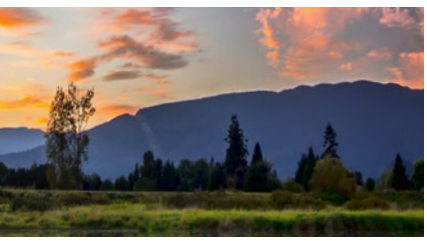

Pricentric INSIGHT: PMPRB Amendments Delayed Again, Due to Take Effect January 1, 2022

Health Canada has once again decided to delay the implementation of the Patented Medicine Prices Review Board (PMPRB) regulatory reforms due to the COVID-19 Pandemic, after they were scheduled to take effect July 1, 2021.

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- Speaking to CNBC on June 7, Biogen CEO Michel Vounatsos announced that the list price of Aduhelm is set to be $56,000 per year, for the first four years at least
- On the news, the Institute for Clinical and Economic Review (ICER) said that the FDA has "failed" in its responsibility to protect patients and families from "unproven treatments with known harms"

THE DETAILS

BALTIMORE, MD, United States – On Monday, June 7, the U.S. Food and Drug Administration (FDA) made its highly anticipated call on Biogen's Alzheimer's candidate, Aduhelm (aducanumab).

The regulatory agency approved the drug under its Accelerated Approval pathway, which allows patients to gain access to the drug even if there remains some uncertainty about its clinical benefit.

Alzheimer's is a complex neurological disorder and one of the most prominent challenges facing healthcare today, with multiple treatments missing the mark in the past. Because of the indication's history, dotted with early stage failures and no new drug approvals since 2003, the FDA's decision will likely serve as a point of reference for future drug approvals in similar indications.

Aduhelm's FDA Journey

The road to approval has been peppered with uncertainty from within pharma, and media speculation added an altogether new kind of pressure to the FDA's committee.

In March 2019, Biogen and its Aduhelm partner Eisai discontinued a number of relevant trials after an independent data monitoring committee indicated they were unlikely to show significant improvements in primary endpoint of change from baseline in CDR-SB score. However, the blow was short lived, and later in the year, the two drugmakers announced plans to seek FDA approval based on results from the Phase III EMERGE trial.

The study ultimately did demonstrate a significant improvement in change from baseline in CDR-SB score, and the company also announced that data from a subgroup in the Phase III ENGAGE Study, who were exposed to a high dose of aducanumab, backed the findings from EMERGE. Carmen Castrillo-Viguera, MD, medical director of clinical development at Biogen, explained at the time: "In this final dataset, EMERGE met the pre-specified primary and secondary endpoints. Post-hoc analyses of data from a subset of patients exposed to high-dose aducanumab in ENGAGE support the findings of EMERGE."

In November 2020, an FDA advisory panel voted heavily against approval of the anti-amyloid antibody for use in the indication, citing conflicting results from various trials outside the ENGAGE study. At the time, the panel gave one yes, eight no and two uncertain votes on the matter, ultimately deciding that the ENGAGE study did not provide strong evidence that supported the effectiveness of Aduhelm for the treatment of Alzheimer's disease.

FDA Approval

In a statement released on the approval date, the FDA noted that it is "well-aware of the attention surrounding this approval," following years of debate surrounding the balance between the drug's efficacy and safety, compared to the huge area of unmet need that Alzheimer's presents.

"We understand that Aduhelm has garnered the attention of the press, the Alzheimer's patient community, our elected officials, and other interested stakeholders. With a treatment for a serious, life-threatening disease in the balance, it makes sense that so many people were following the outcome of this review.

"Further, the data included in the applicant's submission were highly complex and left residual uncertainties regarding clinical benefit. There has been considerable public debate on whether Aduhelm should be approved. As is often the case when it comes to interpreting scientific data, the expert community has offered differing perspectives."

Do Patient Barriers Remain?

Speaking to CNBC on June 7, Biogen CEO Michel Vounatsos announced that the list price of Aduhelm is set to be $56,000 per year, for the first four years at least.

The price tag, according to Vounatsos, is a reflection of "two decades of no innovation" and will allow for Biogen to invest further in its medicines for other indications. He also confirmed that Biogen is working closely with federal health insurance program Medicare as well as private insurers.

The company also released a statement on the matter:

"Price and access are sensitive matters for all groundbreaking innovations. We have engaged extensively with health economists, public health experts and payers about Aduhelm – and we have examined other recent biologic drug innovations. Consistent with our pricing principles, we have established a price for Aduhelm that reflects the overall value this treatment brings to patients, caregivers and society – and one that will enable continuous innovation."

Biogen and its Aduhelm partner, Eisai, simultaneously announced a number of programs intended to support access for all qualified patients, including traditionally underserved populations, with an aim to help patients and their families "understand the disease, navigate the diagnostic journey, and secure culturally competent care and afford treatment." Biogen is set to collaborate with Cigna on a value-based payment agreement to support patient access efficacies and overall access while monitoring patient outcomes.

In an update, Biogen said that it is "engaging with CMS on innovative price and access agreements, including but not limited to, volume-based agreements, that would help support continued sustainability of Medicare budgets. We stand ready to work with payers, including CMS, to create innovative agreements which could lower patient co-payment shares or out-of-pocket expense for patients treated with Aduhelm."

ICER

On the approval, the Institute for Clinical and Economic Review (ICER) said that the FDA had "failed" in its responsibility to protect patients and families from unproven treatments with known harms.

In a statement, the organization explained: "Our review of the evidence was concordant with that of many independent experts: current evidence is insufficient to

demonstrate that aducanumab benefits patients. The avenue forward has seemed clear: another study would be needed to reduce the substantial uncertainty about the drug's effectiveness, a requirement of even greater priority because of the drug's common and potentially serious side effects."

On May 7, ICER published a Draft Evidence Report on the comparative clinical effectiveness and value of Aduhelm for Alzheimer's Disease, rating the drug's evidence as being "insufficient" to demonstrate a net health benefit for patients.

Using the combined results from two contradictory Phase III randomized trials for a base-case cost-effectiveness analysis, ICER concluded there was a small overall health gain commensurate with value-based prices at traditional cost-effectiveness thresholds.

The group determined that at an annual willingness-to-pay threshold of $100,000, Aduhelm would be cost-effective at a price of $2,560 in terms of quality-adjusted life years (QALY) and in terms of equal value of life years gained, $3,960. ICER also noted that for its $150,000 willingness-to-pay threshold, the therapy's QALYs gained would support a price of $4,850, and $6,940 for evLYG.

When adjusted in terms of societal perspective, ICER's annual $100,000 willingness-to-pay threshold was $5,080 when taking evLYG into consideration and $8,290 when considering the $150,000 willingness-to-pay threshold– both well under Biogen's preliminary $56,000 a year price tag.

ICER will now engage with stakeholders, including the manufacturer, to determine how Aduhelm should reflect its value to patients and families and the scale of its potential use.

Reception

This particular drug approval has spurred a portion of the medical industry and the public to criticize the FDA, with Public Citizen's Health Research Group claiming the regulatory body "inappropriately collaborated" with Biogen to "rush the lucrative, unproven treatment."

Dr. Michael Carome, director of the research group, believes that the decision shows a "stunning disregard for science and eviscerates the agency's standards for approving new drugs. Because of this reckless action, the agency's credibility has been irreparably damaged."

He added, "Approving aducanumab despite the lack of evidence of effectiveness plus the well-documented risk of serious harm will raise false hope for millions of Alzheimer's patients and their families, potentially bankrupt the Medicare program because of the drug's projected exorbitant price and impede for years the development of other experimental treatments for the disease."

A number of healthcare professionals are also skeptical about actually giving the therapy to their patients, such as Aroonsiri Howell, M.D, M.P.H., Assistant Professor of Medicine, who took to Twitter to express: "Not only will I NOT prescribe #Aducanumab, I'll share the unconvincing results w/ all colleagues so no one prescribes it."

Health Care System Perspective	Placeholder Annual Price*	Annual Price at $100,000 Threshold	Annual Price at $150,000 Threshold
QALYs Gained	$50,000	$2,560	$4,850
evLYG	$50,000	$3,960	$6,940
Modified Societal Perspective	**Placeholder Annual Price***	**Annual Price at $100,000 Threshold**	**Annual Price at $150,000 Threshold**
QALYs Gained	$50,000	$3,390	$5,750
evLYG	$50,000	$5,080	$8,290

evLYG: Equal value of life years gained, QALY: Quality-adjusted life year

Other HTA bodies also took umbrage with the FDA's decision; BeNeLuxA released a short statement emphasizing that "clinical endpoints such as changes in cognitive scores or dementia scales are considered as the endpoints relevant for HTA agencies in Alzheimer's clinical trials. Biomarker data are not considered sufficient for demonstration of benefit for HTA agencies."

Aduhelm Sets the Bar for Future Alzheimer's R&D

Up until this point, multiple Alzheimer's candidates designed to eliminate or prevent amyloid accumulation failed to demonstrate an improvement in cognition and memory in later-phase clinical trials, even in instances when there was biomarker and magnetic resonance imaging (MRI) evidence that the amyloid was cleared.

Aduhelm is now the first approved treatment directed at the underlying pathophysiology of Alzheimer's disease—the presence of amyloid beta plaques in the brain.

"This FDA drug approval ushers in a new era in Alzheimer's treatment and research," said Maria C. Carrillo, Ph.D., Alzheimer's Association chief science officer. "History has shown us that approvals of the first drug in a new category invigorates the field, increases investments in new treatments and encourages greater innovation. We are hopeful and this is the beginning — both for this drug and for better treatments for Alzheimer's."

By granting the approval via the Accelerated Access pathway, the agency upended years of regulatory precedent, possibly creating new potential and more hope for treatments with considerable potential but perhaps not perfect trial data.

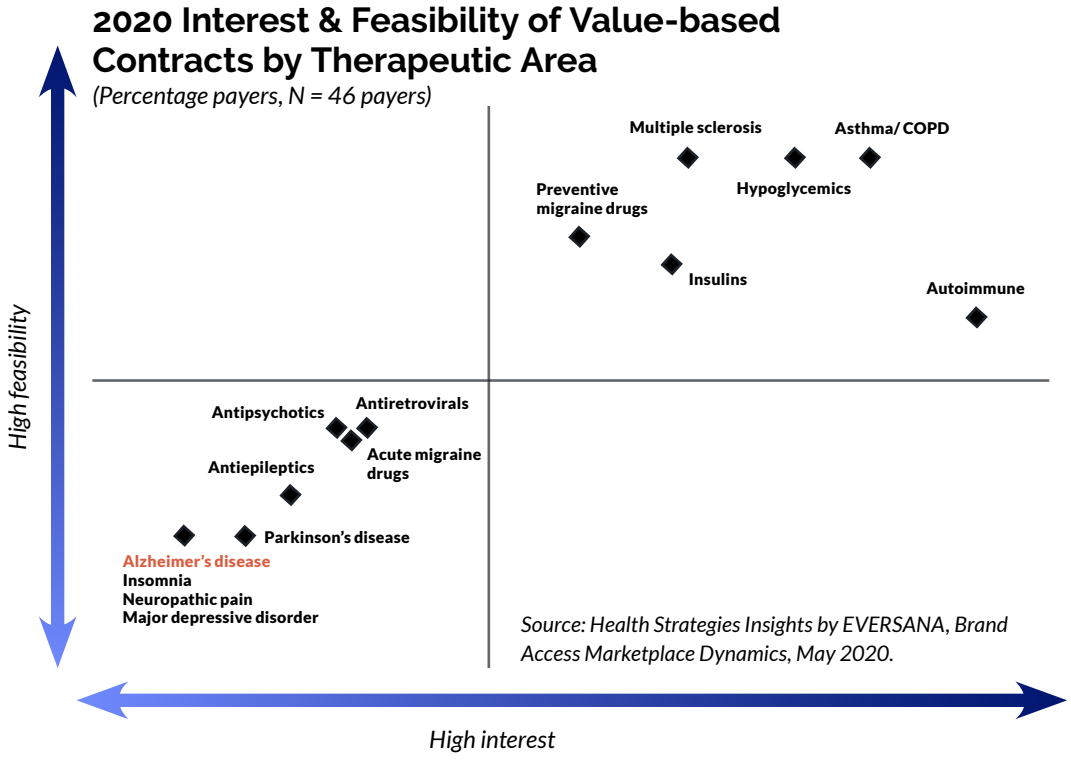
EVERSANA Here to Help

In research conducted by Health Strategies Insights by EVERSANA in 2020, payers reported low interest and feasibility in pursuing value-based agreement for Alzheimer's disease therapies, so the proposed payment agreements mark a dramatic turn of events for this market.

With Aduhelm's entry into the Alzheimer's disease market, how do current brands need to reposition and reaffirm their value proposition to payers and prescribers? Will current and future brands launching into the market be expected to compete aggressively on price or contracting arrangements?

Learn the answers to these questions and many more through Health Strategies by EVERSANA. Reach out to hsiclientservices@eversana.com to discuss further.

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



Pricentric INSIGHT: China's Record-Breaking 5th VBP Round Achieves Average Price Reductions of 56%

Date: June 25, 2021 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: Breaking News, Tender | Keywords: #bidding #centralizedprocurement #generic #hopsital #jointprocurementoffice #pricereduction #smpaa #volumebasedprocurement

PRICENTRIC BRIEF

- During China's fifth round of volume based procurement (VBP) in Shanghai on June 23, 201 manufacturers submitted 355 products, seeking to secure contracts for the 62 drugs covering 451 product specifications up for grabs—In the end, 251 products were chosen from 148 manufacturers
- Sixty-one of the 62 products successfully found bidders in the 5th round, with an average price reduction of 56% across the board
- Round five was record-breaking: It not only involved the highest number of injectables (29), which accounted for 70% of the total purchase volume of this VBP, but also the highest purchase amount (55 billion yuan), which is expected to lead to savings of 25.5 billion yuan each year

THE DETAILS

SHANGHAI, China – During China's fifth round of volume-based procurement (VBP) in Shanghai on June 23, 201 manufacturers submitted 355 products, seeking to secure contracts for the 62 drugs covering 451 product specifications up for grabs. In the end, 251 products were chosen from 148 manufacturers, according to procurement results (with winning bidders and prices) published by Shanghai Sunshine Medical Procurement (SMPAA).

Sixty-one of the 62 products successfully found bidders in the fifth round, with an average price reduction of 56% across the board. Round five was record-breaking. It not only involved the highest number of injectables (29), which accounted for 70% of the total purchase volume of this VBP, but also the highest purchase amount (55 billion yuan)—based on the agreed purchase amount, savings of 25.5 billion yuan are expected each year.

Officials celebrated the inclusion of injectables in this round, as the price reductions—75% for some antibiotics—will greatly benefit patients, and these savings will be used as "funding ammunition" for public hospitals, according to Yao Yu of the Chinese Academy of Social Sciences.

The drugs that found success during VBP cover a spectrum of product specifications, ranging from hypertension, coronary heart disease, diabetes and infectious diseases to chronic illnesses and even cancer (lung, breast and colorectal).

During the bidding, the fiercest competition occurred for rivaroxaban, branded as Xarelto by Bayer. As reported by China's Xinhua news, 20 companies participated in the bidding melee, resulting in a final average price of 0.5 yuan per tablet; the minimum was 0.8 yuan per tablet. In each instance, domestic companies were selected as the winning enterprise.

China's domestic manufacturers won big in round five, with 240 products selected from 138 manufacturers and the remaining 11 products selected from 10 foreign companies, including Fresenius Kabi, Sanofi and Teva. While domestic manufacturers found the greatest success, Chinese officials noted greater participation among foreign companies this time, with 50 companies partaking in the bidding. Sanofi won the bidding for Eloxatin (oxaliplatin) freeze-dried powder for injection 500 mg 1 bottle/box, at a price of CNY 310.51 per box, and Teva won for alfacalcidol soft capsules 0.25μg 10 grains/plate 2 plates/box, at a price of CNY 20.79 per box.

The previous four rounds of VBP covered a total of 157 varieties, with an average price reduction of 53% across all four. Since the VBP initiative launched in 11 cities (4+7 Tender Trial), VBP has led to annual savings of around 67 billion yuan. Now that round five has wrapped, VBP has so far covered 218 drug varieties, and China will continue to expand the scope of centralized drug procurement, according to the National Medical Security Administration.

The fifth round covered the following products, in varying formulations (noted in parentheses):

1. Omega-3 fish oil medium/long-chain fat emulsion (injection)
2. Alfacalcidol (capsules, tablet)
3. Aripiprazole (tablets)
4. Acyclovir (tablets)
5. Esomeprazole sodium (injection)
6. Olopatadine hydrochloride (tablets)
7. Oxaliplatin (injection)
8. Benazepril hydrochloride (tablets)
9. Bepotastine besulphonate (tablets)
10. Cisatracurium benzene sulfonate (injection)
11. Bicalutamide (tablets, capsules)
12. Dabigatran etexilate (capsules)
13. Isosorbide mononitrate (capsules, tablets)
14. Decitabine (injection)
15. Iohexol (injection)
16. Iodixanol (injection)
17. Dutasteride (capsules)
18. Docetaxel (injection)
19. Fasudil hydrochloride (injection)
20. Compound ipratropium bromide (solution for inhalation)
21. Glipizide (controlled-release tablets, tablets)
22. Glycopyrrolate (injection)
23. Ganciclovir (injection)
24. Potassium sodium hydrogen citrate (granules)
25. Gemcitabine hydrochloride (injection)
26. Lansoprazole (injection)
27. Lercanidipine hydrochloride (tablets)
28. Rivaroxaban (tablets)
29. Lipoic acid (injection)
30. Ropivacaine hydrochloride (injection)
31. Potassium chloride (sustained release tablets)
32. Metoprolol tartrate (tablets)
33. Miglitol (tablets)
34. Misoprostol (tablets)
35. Palonosetron hydrochloride (injection)
36. Saxagliptin (tablets)
37. Venlafaxine hydrochloride (sustained-release capsules, sustained-release tablets)
38. Cinacalcet hydrochloride (tablets)
39. Thymalfasin (injection)
40. Promethazine hydrochloride (tablets)
41. Ipratropium bromide (solution for inhalation)
42. Fat emulsion amino acid (17) glucose (11%) (injection)
43. Medium/long-chain fat emulsion (injection)
44. Bendamustine hydrochloride (injection)
45. Paclitaxel (injection)
46. Azithromycin (injection)
47. Budesonide (suspension for inhalation)
48. Fluconazole and sodium chloride (injection)
49. Linezolid glucose (injection)
50. Moxifloxacin hydrochloride (eye drops)
51. Tinidazole (tablets)
52. Cefuroxime sodium (injection)
53. Ceftriaxone sodium (injection)
54. Ceftazidime (injection)
55. Cefazolin sodium (injection)
56. Levofloxacin sodium chloride (injection)

Pricentric INSIGHT: PMPRB Amendments Delayed Again, Due to Take Effect January 1, 2022

Date: June 30, 2021 | Country: CANADA-ONTARIO | Region: NORTH AMERICA | Type: Breaking News, Policy, Pricing & Reimbursement | Keywords: #access #biopharma #clinicaltrial #druglaunch #healthcanada #innovativemedicinescanada #launchsequence #patentedmedicines #pharmacare #pmprb #pmprb11 #pricetransparency #rebates #referencepricing(irp)

PRICENTRIC BRIEF

- Health Canada has once again decided to delay the implementation of the Patented Medicine Prices Review Board (PMPRB) regulatory reforms due to the COVID-19 pandemic, after they were scheduled to take effect July 1, 2021
- The final PMPRB Guidelines take aim at all patented medicines and propose a pharmaco-economic value be applied to drugs with high costs/sales, and PMPRB will rely on an updated reference basket in which two countries where drug prices tend to be higher—the United States and Switzerland—have been swapped out for markets where drug prices tend to be lower; as such, the PMPRB11 will be composed of France, Germany, Italy, Sweden and the UK, as well as newcomers Australia, Belgium, Japan, the Netherlands, Norway and Spain
- Beyond the impact on drug prices, which EVERSANA Data Analysts found to be "significant," industry and patient groups, among others, have warned that the implementation of these new regulations means innovative new medicines will not launch in Canada, the number of clinical trials in Canada will be further reduced, and the life sciences sector will lose out on critical investments

THE DETAILS

Health Canada has once again decided to delay the implementation of the Patented Medicine Prices Review Board (PMPRB) regulatory reforms due to the COVID-19 pandemic, after they were scheduled to take effect July 1, 2021. This is the third time their implementation has been stalled—it was pushed back to January 1, 2021, from July 1, 2020; then to this July; and now finally, until January 1, 2022. The final PMPRB Guidelines take aim at all patented medicines and propose that a pharmaco-economic value be applied to drugs with high costs/sales to gauge how much improvement they offer over existing therapies.

Reference Basket Shake-Up, Costs and Sales Thresholds

Notably, Canada's PMPRB will rely on an updated reference basket in which two countries where drug prices tend to be higher—the United States and Switzerland—have been swapped out for markets where drug prices tend to be lower. Canada's new basket, the PMPRB11, will be composed of France, Germany, Italy, Sweden and the UK, as well as newcomers Australia, Belgium, Japan, the Netherlands, Norway and Spain.

Drugs with a 12-month treatment cost surpassing 150% of GDP per capita and treatments with estimated or actual sales of more than CA$ 50 million per year will be required to undergo additional review, with the potential for substantial price reductions off list prices. PMPRB specified that its new guidelines would be applicable to a medicine depending on when it first received its eight digit Drug Identification Number (DIN)—products that received a DIN before a certain date will be grandfathered in, whereas those that obtain the DIN after this date will be subject to PMPRB review. However, grandfathered and gap medicines are still subject to review, but under somewhat different rules (e.g., no pharmaco-economic assessment, regardless of cost/market size).

In August 2019, the amendments to the Patented Medicines Regulation were announced, which seeks to strengthen and modernize Canada's pricing framework for patented drugs and more significantly empower the PMPRB. PMPRB's mandate is to regulate excessive price, the agency wielding the power to contest the list price of any patented drug by declaring some prices to be an "illegal abuse of patent rights" and challenge drugmakers at an internal tribunal.

Former Canadian Minister of Health, Ginette Petitpas Taylor, called these reforms "the biggest step to lower drug prices in a generation," adding these changes "will lay the foundation" for universal drug coverage under Canada's Pharmacare program.

EVERSANA Analysis | PMPRB11 Impact

As an example, the reference country basket shake-up alone will significantly impact both the highest international price and the median international price comparison metrics, and although Canada is a relatively small market for major drugmakers, lower prices in Canada could potentially spread into the U.S., a major market for pharma companies.

When the PMPRB amendments were first announced, EVERSANA Data Analysts found the change in reference basket means that future manufacturer prices (MNF) of the 10 highest-revenue drugs across all provinces in Canada, including Bayer's Eylea (aflibercept) and MSD's Keytruda (pembrolizumab), could be slashed by over half in some cases.

"We examined a selection of the top revenue generating drugs globally and applied the proposed IRP rule based on current global ex-manufacturer prices derived from Pricentric," explains Max Klietmann, Senior Consultant and Manager of EVERSANA's PriceXpress. "On a cursory level, the impacts in Canada are significant (~20% drop in price for the products considered). This is a massive potential impact in Canada alone, not to mention the potential spillover effect into other markets that either reference Canada formally or look at Canadian prices as a basis for price negotiations."

Industry, Patient Groups Urge Against Amendments

The finalized PMPRB guidelines, which were published at the end of October 2020, ahead of the abandoned January 2021 implementation date, underwent consultation twice, each time garnering negative criticism from the pharmaceutical industry and patient advocacy groups.

Innovative Medicines Canada (IMC), the country's innovative pharmaceutical company bloc, has been most opposed to their implementation. Engaged in litigation against the amendments, IMC is arguing their rollout will "have a negative impact on Canadian patients," because innovative new medicines will not launch in Canada,

the number of clinical trials in Canada will be further reduced, and the life sciences sector will lose out on critical investments. IMC was successful in pushing back against the requirement to disclose confidential rebates, and it was removed before final guidelines were issued.

With these amendments, drugs could not be launched in Canada, or Canada will be late in the launch sequence. Charity and patient advocacy groups likewise argued that the implementation of these guidelines will have repercussions for patient access, leading to patients missing out on new, innovative therapies, as well as the opportunity to partake in clinical trials. Further, patient groups fear that fewer clinical trials in Canada will result in wider inequalities, and without new drugs arriving on the market, doctors will use cheaper, older, and less effective drugs to treat patients.

The industry's swift response to the COVID-19 Pandemic underscored the need to nurture and protect the industry. IMC noted, "As the COVID-19 crisis has shown, Canada's innovative medicines companies are vital to the health and well-being of all Canadians, and we need a regulatory environment that encourages it to grow and thrive."

The bloc further stated, "If Canada wants a vibrant and competitive life sciences sector that ensures access to innovative medicines, a suspension in the PMPRB's regulatory changes would provide the appropriate time and process to consider that the price of innovative medicines are not the primary cost drivers for Canadian public and private drug plans."

IMC has stated that the third delay is "a renewed opportunity to examine the potential impact of these reforms, as well as affording time to generate more effective, alternative solutions." The group has proposed a Guideline Monitoring and Evaluation Plan (GMEP) to assess their impact, with the following key recommendations:

- Prioritize resources to address COVID-19 and stop the PMPRB regulatory reforms given the ongoing pandemic.
- Given the impact of two judicial decisions, PMPRB needs to reconsider and revise its final Guidelines.
- Ensure that the impact of the PMPRB changes is assessed by an independent third party.
- Concentrate on reporting metrics within the PMPRB's mandate.
- Limit PMPRB reporting data resources to regulatory filing information only.
- Replace or supplement the PMPRB's outdated 1987 definition of industry R&D with the more credible alternative recently used by Statistics Canada.

EVERSANA™

EVERSANA has been actively engaging with several clients to assess potential global price impacts resulting from this regulatory change and is able to offer high-level impact studies via PriceXpress™, our tactical price consulting and analysis offering. EVERSANA uniquely has the people, methods, tools and rapidly developed ready-to-go models and approaches to assist businesses in navigating Canadian and Global Pricing changes and interdependencies. This expertise is built on our combined decades of experience solving problems in and building tools for global pricing intelligence, price referencing tools, global visibility and product launch expertise and has put us in a trusted position to advise clients on how to handle these changes.

Netherlands' Parallel Procedures Pilot Expedites Registration, Reimbursement of New Medicines

Date: June 22, 2021 | Country: NETHERLANDS | Region: EUROPE | Type: Drug Approval, Pricing & Reimbursement, Regulation | Keywords: #astellas #avacopan #bayer #vig #zin #pilot #ciltacabtageneautoleucel #finerone #insmed #janssen #meb #novonordisk #gvs #parallelproceduresmebzin

PRICENTRIC BRIEF:

- After coming into fruition in May 2019, the Netherlands' Parallel Procedures MEB-ZIN pilot has allowed for concurrent drug registration review by the Medicines Evaluation Board (MEB) and reimbursement review by the Zorginstituut (ZIN), whereas typically a drug must first pass quality, safety and efficacy assessment by MEB before ZIN can decide on its eligibility for inclusion in the Medicines Reimbursement System (GVS)
- So far, Novo Nordisk's Rybelsus (semaglutide) for insufficiently controlled type 2 diabetes mellitus (T2D) and Insmed's Arikayce (amikacin liposomal suspension for inhalation) for non-tuberculosis mycobacterial (NTM) lung infections caused by Mycobacterium avium complex (MAC) have successfully completed the pilot, each receiving an expeditious recommendation for inclusion in the GVS by ZIN—according to the Dutch Association of Innovative Medicines (VIG), Rybelsus and Arikayce partaking in the Parallel Procedure "resulted in an average time saving of three months"
- Following these two medicines are Astellas' Evrenzo (roxadustat) for anemia due to chronic kidney disease (CKD), Bayer's finerenone for chronic kidney damage and T2D, Vifor Pharma's avacopan for ANCA-associated vasculitis (AAV), and Janssen's ciltacabtagene autoleucel (cilta-cel) for multiple myeloma (MM), with Janssen's CAR-T therapy as the first inpatient medicine to partake in the Parallel Procedure Pilot

THE DETAILS

AMSTERDAM, Netherlands – After coming into fruition in May 2019, the Netherlands' Parallel Procedures MEB-ZIN pilot has allowed for concurrent drug registration review by the Medicines Evaluation Board (MEB) and reimbursement review by the Zorginstituut (ZIN), whereas typically a drug must first pass quality, safety and efficacy assessment by MEB before ZIN can decide on its eligibility for inclusion in the Medicines Reimbursement System (GVS).

So far, Novo Nordisk's Rybelsus (semaglutide) for insufficiently controlled type 2 diabetes mellitus (T2D) and Insmed's Arikayce (amikacin liposomal suspension for inhalation) for non-tuberculosis mycobacterial (NTM) lung infections caused by Mycobacterium avium complex (MAC) have successfully completed the pilot, each receiving a recommendation for inclusion in the GVS by ZIN.

According to Dineke Amsing, Access and Good Use of Medicines Manager, the Dutch Association of Innovative Medicines (VIG), Rybelsus and Arikayce partaking in the Parallel Procedure "resulted in an average time saving of three months," expediting the entire process from registration to reimbursement.

Following these two medicines are Astellas' Evrenzo (roxadustat) for anemia due to chronic kidney disease (CKD), Bayer's finerenone for chronic kidney damage and T2D, Vifor Pharma's avacopan for ANCA-associated vasculitis (AAV), and Janssen's CAR-T therapy, ciltacabtagene autoleucel (cilta-cel) for multiple myeloma (MM). Notably, Janssen's CAR-T therapy is the first inpatient medicine to partake in the Parallel Procedure Pilot.

Both procedures (registration and reimbursement) for avacopan and cilta-cel will commence in the second half of 2021.

For Amsing, the entry of Janssen's inpatient therapy offers experience "we can use to further streamline the procedures for registration and reimbursement," a

major win, as VIG has backed embedding this pilot as an option for reimbursement applications.

Parallel Procedure Eligibility

Besides specific timestamps, the main criteria to be eligible in the pilot include: reimbursement on Appendix 1B of the GVS must be requested for the drug, the drug will most likely be placed in the "lock for expensive medicines," and the responsible company must participate actively during the pilot procedure to further shape the methodology.

If a drug has been simultaneously entered into the BeNeLuxA or EUnetHTA Project, among other schemes, there's a high chance marketing authorization will not be granted; or if two similar medicines meet the criteria for inclusion in the pilot, then a drug is not eligible for the Parallel Procedure.

Changes to Germany's NUB Process to Accelerate Access to ATMPs

Date: June 18, 2021 | Country: GERMANY | Region: EUROPE | Type: Policy, Pricing & Reimbursement | Keywords: #access #allianceforregenerativemedicine #atmp #cellandgenetherapy #drgcode #hospital #inek #remuneration

PRICENTRIC BRIEF:

- The German Parliament has approved legislation tweaking Germany's NUB process, which allows hospitals to submit requests for reimbursement for new and innovative diagnostic and treatment methods, as well as for associated care, that have not yet obtained a diagnosis-related group (DRG) code—It could take effect as soon as August and accelerate access to Advanced Therapy Medicinal Products (ATMPs), including cell and gene therapies
- The new law would permit NUB requests to be sent to the Institute for the Hospital Remuneration System (InEK) twice, by October 31 and April 30, and InEK has two months to respond—but without its approval, negotiations can still take place
- Additionally, the new law would allow hospitals to submit NUB inquiries for all services provided in conjunction with administering new pharmaceuticals, including ATMPs, ahead of marketing authorization, and the NUB agreement would take effect on the product's marketing authorization date

THE DETAILS

BERLIN, Germany – The German Parliament has approved legislation allowing NUB inquires twice a year, which is anticipated to accelerate access to Advanced Therapy Medicinal Products (ATMPs), including cell and gene therapies, by removing bureaucratic limitations that have delayed their availability in hospitals, announced the Alliance for Regenerative Medicine (ARM).

Since ATMPs are highly innovative and usually administered at hospitals, where physician care and other associated services must be reimbursed, the NUB process allows hospitals to submit requests for reimbursement for new and innovative diagnostic and treatment methods, as well as for associated care, that have not yet obtained a diagnosis-related group (DRG) code.

Currently, hospitals are allowed to submit NUB requests to the Institute for the Hospital Remuneration System (InEK) only once per year for approval, before reimbursement of these extra services are subject to negotiations between the individual hospital and insurance funds.

The new law would permit NUB requests to be sent to InEK twice, by October 31 and April 30, and InEK has two months to respond—if it does not in time, negotiations on NUB payment can occur without InEK approval. Additionally, the new law would allow hospitals to submit NUB inquiries for all services provided in conjunction with administering new pharmaceuticals, including ATMPs, ahead of marketing authorization, and the NUB agreement would take effect on the product's marketing authorization date.

According to Paige Bischoff, the Alliance for Regenerative Medicine's (ARM) Senior Vice President of Global Public Affairs, "ARM applauds this action to reduce a bureaucratic hurdle that stood in the way of patient access to durable, and potentially curative, ATMPs. The legislation makes it easier for German hospitals to provide life-changing cell and gene therapies to patients, many of whom have few other treatment options."

The NUB process remains the same, besides the addition of a second deadline and the ability to inquire about NUB before the drug's approval. The law is part of a larger health package and could be voted on by the Bundesrat by the end of June and, without any delays, could become law in August.

MHRA Nixes Confirmatory Clinical Trial Requirement for Biosimilars

Date: June 16, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Type: Biosimilar, Regulation | Keywords: #britishbiosimilarassociation #confirmatorytrial #humira #lucentis #mhra #patentexpiration #savings

PRICENTRIC BRIEF:

- The United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) has removed the requirement for biosimilar drugs to undergo confirmatory clinical trials in humans before being approved for use
- As quoted by The Telegraph, Mark Samuels, Chief Executive of the British Biosimilars Association, said, "The new guidance puts the UK ahead of the rest of Europe when it comes to regulatory innovation and could provide a further catalyst to a biosimilar boom in the next decade"
- With the European patents for more than 30 biosimilars set to expire over the next 15 years and biologics accounting for 80% of NHS spending, the NHS could save "hundreds of millions of pounds" with this policy amendment, said Samuels

THE DETAILS

LONDON, United Kingdom – The United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) has removed the requirement for biosimilar drugs to undergo confirmatory clinical trials in humans before being approved for use, reported The Telegraph.

After years of monitoring and data collection, MHRA believes that 50 to 60 laboratory tests are now enough to ensure the safety and efficacy of biosimilars, thereby supporting the regulator's decision to nix the requirement for confirmatory testing.

MHRA's European and United States counterparts have yet to augment their guidance on biosimilars, which means the UK anticipates being a first-launch market for these products, and the NHS will receive biosimilars a year earlier.

As quoted by The Telegraph, Mark Samuels, Chief Executive of the British Biosimilars Association, said, "The new guidance puts the UK ahead of the rest of Europe when it comes to regulatory innovation and could provide a further catalyst to a biosimilar boom in the next decade."

Over the next 15 years, the European patents for more than 30 biosimilars are set to expire, including for Novartis' Lucentis (ranibizumab), which is good news for the UK, considering 80% of the most expensive drugs used by the NHS are biologics.

Biosimilars to AbbVie's Humira (adalimumab) are expected to save expected to save the NHS £300 million by the year's end, and with more patents set to expire in the coming years, and biosimilars expected to arrive to market earlier, the NHS could save "hundreds of millions of pounds," said Samuels.

First Patient Treated With Zolgensma in United Kindgom

Date: June 1, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Type: | Keywords: #atrophy #baby #genetherapy #muscular #novartis #patient #sma #spinal #zolgensma

PRICENTRIC BRIEF:

- A five-month-old has become the first patient to be treated with Novartis' Zolgensma (onasemnogene abeparvovec) in the UK, following the closing of a "landmark" deal for the therapy in March
- The recipient, Arthur Morgan, was born six weeks premature in December and ultimately underwent the gene therapy infusion at the end of May after being diagnosed with spinal muscular atrophy (SMA) less than three weeks earlier
- NHS England and Novartis signed an agreement in March to make Zolgensma available for SMA type 1 patients on the UK's NHS

THE DETAILS

LONDON, United Kingdom – A five-month-old has become the first patient to be treated with Novartis' Zolgensma (onasemnogene abeparvovec) in the UK, following the closing of a "landmark" deal for the therapy in March.

The recipient, Arthur Morgan, was born six weeks premature in December and ultimately underwent the gene therapy infusion at the end of May after being diagnosed with spinal muscular atrophy (SMA) less than three weeks earlier.

He received the dose at Evelina London Children's Hospital on 25 May.

NHS England and Novartis signed an agreement in March to make Zolgensma available for SMA type 1 patients on the UK's NHS.

The one-time gene therapy can help babies to reach milestones such as breathe without a ventilator, sit up on their own and move and walk after a single injection, but has a £1.79 million per dose price tag.

However, the two parties struck a deal to secure the innovative gene therapy at a "substantial" confidential discount.

In the document, the organization determined that because of the uncertainty in the clinical data, the cost-effectiveness estimates for Zolgensma treating type 1 SMA are uncertain. However, they are likely to be within a range of what NICE considers an effective use of NHS resources for highly specialized technologies.

Further, the consultation clarified that because of the limited trial data for children aged 7 to 12 months, their treatment should be discussed by a national multidisciplinary team.

Up until now, NICE has recommended the disease-modifying therapy Spinraza (nusinersen) for some people with pre-symptomatic SMA and types 1, 2 or 3 SMA as part of a managed access agreement.

Ultra-Orphan Validations to Expire After 2 Years, Decides Scottish Medicines Consortium

Date: June 15, 2021 | Country: UNITED KINGDOM | Region: EUROPE | Type: HTA, Policy | Keywords: #datacollection #mhra #nhsscotland #raredisease #scottishmedicinesconsortium #ultraorphanpathway

PRICENTRIC BRIEF:

- The Scottish Medicines Consortium has agreed that from September 1, 2021, ultra-orphan validation decisions will expire after two years, in an update to the ultra-orphan validation process
- After two years, if a product has Medicines and Healthcare Products Regulatory Agency (MHRA) marketing authorization, if there are eligible patients in NHS Scotland, and if no submission is expected, then SMC will issue Not Recommended advice
- For ultra-orphan pathway consideration, companies are advised by SMC to seek confirmation that their medicine meets the definition for such a product by completing an ultra-orphan proforma, which SMC then reviews before conducting an initial assessment of the clinical and cost-effectiveness of the medicine to highlight uncertainties that inform the data collection stage of the ultra-orphan pathway

THE DETAILS

EDINBURGH, United Kingdom – The Scottish Medicines Consortium has agreed that from September 1, 2021, ultra-orphan validation decisions will expire after two years, in an update to the ultra-orphan validation process.

After two years, if a product has Medicines and Healthcare Products Regulatory Agency (MHRA) marketing authorization, if there are eligible patients in NHS Scotland, and if no submission is expected, then SMC will issue Not Recommended advice.

For ultra-orphan pathway consideration, companies are advised by SMC to seek confirmation that their medicine meets the definition for such a product by completing an ultra-orphan proforma, preferably ahead of receiving an opinion from the European Medicines Agency (EMA).

SMC then reviews the proforma and will confirm whether the medicine has been validated as ultra-orphan within eight weeks—confirmation is necessary before the company makes a submission for initial assessment.

The agency's initial assessment of the clinical and cost-effectiveness of the medicine aims to highlight uncertainties that inform the data collection stage of the ultra-orphan pathway, and SMC will use a "broad framework" to appraise the medicine, accounting for the nature of the disease, impact of the medicine and value, among other factors.

Nordics Announce Another Joint Tender

Date: June 14, 2021 | Country: DENMARK, ICELAND, NORWAY | Region: EUROPE, NORDICS | Type: Tender | Keywords: #amgros #crossbordercollaboration #drugsupply #hospital #jointtender #pricingandreimbursement

PRICENTRIC BRIEF:

- Denmark, Iceland and Norway have announced another joint Nordic tender, which will focus on price, security of supply, and the environment—specifically, medicines "that are potentially critical for supply or where there is a de facto monopoly"
- The list includes ampicillin, anagrelide, ceftazidime, cefuroxime, ciprofloxacin, gentamicin, meropenem, methotrexate, metronidazole, ondansetron, paracetamol and vancomycin
- The procurement period for tenders will run from April 1, 2022, through March 1, 2024, with the possibility of extension

THE DETAILS

COPENHAGEN, Denmark – Denmark, Iceland, and Norway have announced another joint Nordic tender, which will focus on price, security of supply and the environment.

In this upcoming tender, Denmark, Iceland and Norway are focusing on medicines "that are potentially critical for supply or where there is a de facto monopoly." The list includes ampicillin, anagrelide, ceftazidime, cefuroxime, ciprofloxacin, gentamicin, meropenem, methotrexate, metronidazole, ondansetron, paracetamol and vancomycin.

The procurement period for tenders will run from April 1, 2022, through March 1, 2024, with the possibility of extension.

Back in September 2018, the Ministers of Health from Denmark and Norway signed a common agreement of intent, followed in April 2019 by Icelandic's Minister of Health. While the three countries differ on organizational, regulatory and logistical procedures, it was possible to find a common solution, they noted.

In April 2019, the Nordic countries announced their first joint tender, which intended to combine Denmark, Iceland and Norway into "one large, attractive Nordic market for selected hospital pharmaceuticals," particularly older medicines with expired patents that have been on the market for some time and have little competition. For the first go, the procurement agencies in these three countries focused on the following drugs for hospital use: methotrexate, anagrelide, meropenem, ondansetron, gentamycin, and paracetamol.

The first tendering procedure took one year and two months because the Denmark, Iceland, and Norway experienced many bumps along the way, including political and legal impediments in carrying out cross-border tendering procedures.

Biosimilar Consumption Grew 10.4% in Italy in 2020

Date: June 21, 2021 | Country: ITALY | Region: EUROPE | Type: Biosimilar | Keywords: #aifa #biologic #consumption #egualia #folitropinalfa #pegfilgrastim

- In 2020, biosimilar products recorded a growth in consumption of 10.4% compared to the previous year, while there was a 13.9% contraction in sales of all other biologic drugs, according to Italy's Accessible Pharmaceutical Industries, Egualia (formerly Assogenerici)
- In 2020, the biosimilar versions of these drugs comprised 35% of national consumption, up 5% from the prior year, with filgrastim, rituximab, infliximab, epoetin, and adalimumab biosimilars surpassing the market share of their respective reference biologics—in particular, filgrastim absorbed 96.08% of the market by volume, rituximab 91.41%, infliximab 90.99%, epoetin 88.16%, and adalimumab 73.24%
- At a regional level, Valle d'Aosta and Piedmont both had consumption shares of 76.6%, up 5% from the previous year, followed by Marche (72.4%), Emilia Romagna (69.6%), Basilicata (60.3%) and Tuscany (58.6%)

THE DETAILS

ROME, Italy – In 2020, biosimilar products recorded a growth in consumption of 10.4% compared to the previous year, while there was a 13.9% contraction in sales of all other biologic drugs, according to Italy's Accessible Pharmaceutical Industries, Egualia (formerly Assogenerici).

Last year there were 15 biosimilar molecules on the Italian market: adalimumab, bevacizumab, enoxaparin, epoetin, etanercept, filgrastim, follitropin alfa, infliximab, insulin glargine, insulin lispro, pegfilgrastim, rituximab, somatropin, teriparatide and trastuzumab.

In 2020, the biosimilar versions of these drugs comprised 35% of national consumption, up 5% from the prior year, whereas originator drugs took up 65%, down from 70% from the year before.

Filgrastim, rituximab, infliximab, epoetin, and adalimumab biosimilars surpassed the market share of their respective reference biologics—in particular, filgrastim absorbed 96.08% of the market by volume, rituximab 91.41%, infliximab 90.99%, epoetin 88.16%, and adalimumab 73.24%.

At a regional level, Valle d'Aosta and Piedmont both had consumption shares of 76.6%, up 5% from the previous year, followed by Marche (72.4%), Emilia Romagna (69.6%), Basilicata (60.3%), Tuscany (58.6%). At the opposite end were Umbria (14.1%), Liguria (17.4%) and Trentino Alto Adige (21.1%).

EU Proposes Multilateral Trade Action Plan to Promote Broad Production & Fair Access in COVID-19

Date: June 8, 2021 | Country: BELGIUM | Region: EUROPE | Type: Policy | Keywords: #covid #eu #multilateral #plan #proposal #trade #vaccine #wto

PRICENTRIC BRIEF:

- To broaden the production and fair access of COVID-19 vaccines and treatments, the European Union (EU) has called for the World Trade Organization (WTO) members to commit to a proposed multilateral trade action plan
- In addition to employing licensing agreements, tiered pricing and investments in manufacturing in developing countries, the EU expects all vaccine producers and developers to ramp up supplies to vulnerable nations
- If voluntary licenses are unsuccessful in expanding production, the EU recommends government-issued targeted licenses which allow a company to produce a vaccine without the consent of a patent holder—It called for the WTO to take the reins on compulsory licensing within its existing agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

THE DETAILS

BRUSSELS, Belgium — To broaden the production and fair access of COVID-19 vaccines and treatments, the European Union (EU) has called for the World Trade Organization (WTO) members to commit to a proposed multilateral trade action plan.

Executive Vice President and Commissioner for Trade Valdis Dombrovskis said: "In reality, the main problem at this moment relates to the lack of sufficient manufacturing capacity to rapidly produce the required quantities. The objective must be to ensure that any available and adequate manufacturing capacity anywhere in the world is used for the COVID-19 vaccines production."

In its proposal, the EU seeks to achieve free trade of COVID-19 vaccines and treatments as well as expanded production and equitable prices.

Countries that produce vaccines are expected to offer a fair volume for export. The EU said it does not support restrictions in the supply to the COVAX facility.

In addition to employing licensing agreements, tiered pricing and investments in manufacturing in developing countries, the EU expects all vaccine producers and developers to ramp up supplies to vulnerable nations.

The EU commended BioNTech and Pfizer, Johnson & Johnson and Moderna for having already committed to delivering 1.3 billion doses this year to middle-income countries at lower cost and to low-income countries at no profit.

Further, the EU highlighted voluntary licenses as the best method of expanding production and sharing of expertise. If voluntary cooperation is unsuccessful, the EU recommends government-issued targeted licenses, which allow a company to produce a vaccine without the consent of a patent holder.

It called for the WTO to take the reins on compulsory licensing within its existing agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

President von der Leyen said: "The European Union authorized exports of around half of the total amount of vaccines produced in Europe. Our immediate, urgent goal is to ensure equitable access for low – and middle-income countries, to share vaccines wider and faster. And we continue to help ramping up production. The EU proposes concrete short and medium term solutions to ensure universal access at affordable prices."

PHARMIG Urges "Permanent Fixation" Into Law of Austria's Off-Patent Drug Pricing Regulations

Date: June 23, 2021 | Country: AUSTRIA | Region: EUROPE | Type: Policy | Keywords: #biosimilar #generic #nationalcouncil #offpatent #pharmig #priceband #pricerange

PRICENTRIC BRIEF:

- Austria's National Council has voted to extend to 2023 pricing regulations in place since 2017 for off-patent drugs (i.e., generics and biosimilars), which, according to the Association of the Austrian Pharmaceutical Industry (PHARMIG), ensures certainty for drug manufacturers; however, the Association wants these regulations officially promulgated to prevent any supply disruptions in the future, due to a lack of faith in the permanence of these regulations
- The "price band" stipulates how and when companies must reduce their products, including generics, but the National Council's extension of pricing regulations excluded the "price range" that dictates the price of drugs with the same active ingredients cannot be a maximum of 30% higher than that of the cheapest supplier
- PHARMIG Secretary General Alexander Herzog said, "We therefore welcome the extension of the generic and biosimilar price regulation until the end of 2023, but we see a permanent fixation of this regulation and a continuation of the price range as inevitable"

THE DETAILS

VIENNA, Austria – Austria's National Council has voted to extend to 2023 pricing regulations in place since 2017 for off-patent drugs (i.e. generics and biosimilars), which according to the Association of the Austrian Pharmaceutical Industry (PHARMIG) ensures certainty for drug manufacturers; however, the Association wants these regulations officially promulgated to prevent any supply disruptions in the future, due to a lack of faith in the permanence of these regulations.

PHARMIG is "striving to incorporate the regulations into permanent law," to not only ensure the continuous supply of generics and biosimilars, the backbone of sustainability for Austria's health system, but to also prevent a "further downward price spiral." These regulations mean some degree of certainty for pharmaceutical companies, given they've been in place since 2017, and codifying them into law provides a stalwart blueprint.

For example, the "price band" stipulates how and when companies must reduce their products—the price of a first generic may not exceed 50% of the price of the originator drug, and the following generic must be at least 18% cheaper than the first. PHARMIG sees the value of this rule, as 22 biosimilars are available in Austria, which has led to savings of 247 million euros between 2017 and 2019.

However, the National Council's extension of pricing regulations excluded the "price range" that dictates the price of drugs with the same active ingredients cannot be a maximum of 30% higher than the cheapest supplier. While "far-reaching," said PHARMIG, the rule nonetheless gave pharmaceutical companies "a certain degree of planning security," ensuring "diversity and security in the supply of medicines."

PHARMIG Secretary General Alexander Herzog said, "Patients must be able to trust that their existing medication will also be secured in the future. In addition, the lower therapy costs mean that more patients can be treated earlier. We therefore welcome the extension of the generic and biosimilar price regulation until the end of 2023, but we see a permanent fixation of this regulation and a continuation of the price range as inevitable."

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European Commission Purchases Additional 150M Moderna Vaccine Doses

Date: June 23, 2021 | Country: BELGIUM | Region: EUROPE | Type: Other | Keywords: #commission #european #moderna #pandemic #purchase #union #vaccine

PRICENTRIC BRIEF:

- The European Commission has purchased an additional 150 million doses of Moderna's COVID-19 Vaccine, expanding on its previous agreement and bringing the European Union's total amount of COVID-19 vaccine doses to 4.4 billion
- The amendment to the Union's second contract with Moderna will see the doses arrive in the bloc from 2022, as well as providing for the possibility to purchase vaccines adapted to virus variants and vaccines for pediatric use and booster vaccines
- Under the contract, member states also have the possibility to resell or donate doses to countries in need outside the EU or through the COVAX facility

THE DETAILS

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Under the contract, member states also have the possibility to resell or donate doses to countries in need outside the EU or through the COVAX facility.

In a tweet, EU President Ursula von der Leyen announced: "Today we secured 150 million additional doses of the @moderna_tx vaccine. We are also securing a contract for new generation vaccines. It will give us the flexibility we need to procure adapted #COVID19 vaccines to protect people from new variants of the virus."

Moderna's vaccine is currently approved for people aged 18 years and older in the EU.

On June 17, the United States government also purchased an additional 200 million doses of Moderna's vaccine, including an option to purchase other COVID-19 vaccine candidates from Moderna's pipeline.

European Council & Parliament Reach Informal Deal on Joint EU HTA

Date: June 24, 2021 | Country: BELGIUM | Region: EUROPE | Type: Breaking News, HTA, Policy | Keywords: #bloc #collaboration #commission #crossborder #eu #european #hta #joint #parliament #union

PRICENTRIC BRIEF:

- The European Council and European Parliament have made a "decisive breakthrough" on a legislative proposal for joint health technology assessment (HTA) in the Union
- The two parties reached a provisional agreement on Tuesday June 22, signing off the implementation of a regulation that will "dramatically reduce duplications of clinical assessments, ensure sustainable cooperation on HTA and provide us with a framework to better face health issues, such as rare diseases, personal medicine, and orphan medicines," according to German MEP Tiemo Wölken
- Following the provisional agreement, the new rules will begin to take effect three years from the entry into force of the regulation, however, the regulation will now have to be formally adopted by the Council and the European Parliament before it can enter into force

THE DETAILS

BRUSSELS, Belgium – The European Council and European Parliament have made a "decisive breakthrough" on a legislative proposal for joint health technology assessment (HTA) in the Union.

The two parties reached a provisional agreement on Tuesday June 22, signing off the implementation of a regulation that will "dramatically reduce duplications of clinical assessments, ensure sustainable cooperation on HTA and provide us with a framework to better face health issues, such as rare diseases, personal medicine, and orphan medicines," according to German MEP Tiemo Wölken.

At the start of June, the joint HTA dossier reached interinstitutional negotiations three years after its initial proposal.

The legislative proposal from the European Commission was then discussed at EU-level with aims to boost EU cooperation between Member States on health technology assessment.

It will replace the current system of EU-funded project-based cooperation between Member States on health technology assessment with a permanent framework for joint work.

Following the provisional agreement, the new rules will begin to take effect three years from the entry into force of the regulation; however, the regulation will now have to be formally adopted by the Council and the European Parliament before it can enter into force.

In a tweet on his official account, Tiemo Wölken outlined a number of the agreements that came out of the HTA meeting:

- More transparency of reports and work in relation to JCA & JSC
- Clear provisions on stakeholder selection & greater stakeholder involvement in joint work
- Safeguards on uptake of JCA (annexing final JSC & report on use in national HTAs)
- Clear definition on divergent scientific reports
- Shorter timeline for full implementation of scope
- Clear voting mechanism for Coordination group on political strategic issues & scientific technical issues

The dossier's aims have previously been outlined by the European Council as:

General objectives:

- Ensure a better functioning of the internal market;
- Contribute to a high level of human health protection.

Specific objectives:

- Improve the availability of innovative health technologies for EU patients;
- Ensure efficient use of resources and strengthen the quality of HTA across the EU;
- Improve business predictability.

Operational objectives:

- Promote convergence in HTA tools, procedures and methodologies;
- Reduce duplication of efforts for HTA bodies and industry;
- Ensure the use of joint outputs in Member States;
- Ensure the long-term sustainability of EU HTA cooperation.

Ahead of the interinstitutional negotiations, EUCOPE also underlined a number of considerations to be included in the discussions to help mitigate any negative changes to the collaboration:

- Sufficient management of evidentiary uncertainties for OMPs and ATMPs to prevent delays in patients' access
- Mandatory uptake of joint clinical assessment at national level to reduce regulatory burden
- Early scientific advice for all manufacturers for increased predictability

Reception

The European Commission welcomed the decision, believing that the decision will "improve the availability of innovative health technologies such as innovative medicines and certain medical devices for EU patients, ensure efficient use of resources and strengthen the quality of HTA across the EU."

Commissioner for Health and Food Safety, Stella Kyriakides, said she is "pleased that the European Parliament and the Council have reached a long-awaited political agreement on the Health Technology Assessment Regulation," calling the move a "significant step forward to enable joint scientific assessments of promising treatments and medical devices at EU level."

Marta Temido, Minister of Health of Portugal, also added:

"We have reached a decisive breakthrough on a new law which will benefit patients, manufacturers of health technologies and member states' health systems. We will all stand to gain when innovative, safe and effective health technologies can reach the market more quickly. EU-level cooperation is the way forward to make this happen."

Access Consortium Publishes Strategic Plan 2021-2024

Date: June 28, 2021 | Country: AUSTRALIA, CANADA-ONTARIO, SINGAPORE, SWITZERLAND, UNITED KINGDOM | Region: ASIA & SOUTH PACIFIC, EUROPE, NORTH AMERICA | Type: Regulation | Keywords: #accessconsortium #acss #covid19 #drugreview #healthcanada #healthcaresystem #hsa #hta #innovation #mhra #pharmacovigilance #realworlddata #realworldevidence #swissmedic #tga #vaccine

PRICENTRIC BRIEF:

- Access Consortium members the Therapeutic Goods Administration (TGA) of Australia, Health Canada, the Health Sciences Authority (HSA) of Singapore, Swissmedic, and the Medicines and Health Care Products Regulatory Agency (MHRA) of the United Kingdom have published their Strategic Plan 2021-2024, which envisions further alignment on drug regulations and work-sharing to provide faster access to safe, effective and high-quality medicines
- Through 2024, the Consortium intends to strengthen work-sharing initiatives, increasing the number of applications and variety of health products assessed by the regulators, optimizing work-sharing through greater alignment, strengthening collaboration by supporting Consortium participation in international initiatives, exploring best practices to further optimize resources, and capturing lessons learned to innovate work-sharing
- Additionally, the Consortium foresees greater involvement in clinical trial design, including focusing on real-world data or evidence (RDW; RWE) and exploring the use of pharmacovigilance and RWD to support early entry to market of vaccines and therapeutics for COVID-19 and other diseases, integrating healthcare systems in their approach, and working with national health technology assessment (HTA) bodies

THE DETAILS

LONDON, United Kingdom – Access Consortium members the Therapeutic Goods Administration (TGA) of Australia, Health Canada, the Health Sciences Authority (HSA) of Singapore, Swissmedic, and the Medicines and Health Care Products Regulatory Agency (MHRA) of the United Kingdom have published their Strategic Plan 2021-2024, which envisions further alignment on drug regulations and work-sharing to provide faster access to safe, effective and high-quality medicines.

The Access Consortium has so far successfully evaluated numerous medicines simultaneously, including first-in-world medicines, with many more currently awaiting review. This increased regulatory alignment seeks to reduce patient wait times to access new medicines, and the COVID-19 Pandemic showed that regulatory innovation is crucial to address the urgent need for health products, said the Consortium.

Through 2024, the Consortium intends to strengthen work-sharing initiatives, increasing the number of applications and variety of health products assessed by the regulators, optimizing work-sharing through greater alignment, strengthening collaboration by supporting Consortium participation in international initiatives, exploring best practices to further optimize resources, and capturing lessons learned to innovate work-sharing.

Additionally, the Consortium will maximize collaboration through a health product's lifecycle by considering collaboration on clinical trial design and/or sponsor advice, exploring using real-world data (RWD) or real-world evidence (RWE) in clinical trial design, establishing collaboration and scientific information sharing within the Consortium on risk-management, pharmacovigilance, and post-market safety, exploring the use of pharmacovigilance and RWD to support early entry to market of vaccines and therapeutics for COVID-19 and other diseases and considering further collaboration on Good Practice (GxP) inspections.

To integrate a healthcare systems approach, the Consortium intends to strengthen and leverage regulatory scientific capacity for emerging technologies and innovative products, explore collaboration with national health technology assessment (HTA) organizations, as well as explore a more collaborative aligned healthcare systems approach, integrating healthcare system partners throughout the lifecycle of innovative products and fostering links between these systems and regulatory oversight.

Lastly, the Consortium will use the following points to measure the success of the initiative over the next few years:

- Increase in applications to Access at the same time or soon after filed with other major medicines regulators
- Increase in number of products made available to patients via Access
- Increase in diversity of products assessed via Access
- Decrease in average time to market for products assessed under Access
- Reduced effort and duplication for both regulators and industry
- Increased collaboration on the alignment of products made available to patients via Access with healthcare system needs
- Increased collaboration on global GxP inspections
- Increase in number of ICH guidelines implemented through Access collaboration.

The Consortium formed in 2007 as "ACSS," initially composed of the national drug regulators from Australia, Canada, Singapore and Switzerland, before the UK's MHRA joined in October 2020.

France's ATU Scheme Reform to Come Into Force From July

Date: June 28, 2021 | Country: FRANCE | Region: EUROPE | Type: Editor's Choice, HTA, Policy | Keywords: #access #atu #bill #cu #data #decree #eaa #france #innovation #patient #plfss #rtu

PRICENTRIC BRIEF:

- France has made changes to its long-standing Authorization for Temporary Use (ATU) and Recommendation for Temporary Use (RTU) systems via the Social Security Finance Bill 2021 (PLFSS 2021) – and the changes are set to be implemented from next month
- The French alternative reimbursement pathway is currently divided into six systems, but under the reforms, the methods will be combined, and just two new mechanisms will be introduced: Early Access Authorization (EAA) and Compassionate Use (CU)
- The new EAA system will be used primarily for innovative medicines and will be subject to the relevant company's commitment to apply for an MA or for registration on a reimbursement list, within a specific timeline. The CU pathway will instead be used for certain medicines in specific therapeutic indications and for which, subject to exceptions, no development process is contemplated

THE DETAILS

PARIS, France – France has made changes to its long-standing Authorization for Temporary Use (ATU) and Recommendation for Temporary Use (RTU) systems via the Social Security Finance Bill 2021 (PLFSS 2021).

As it stands, the ATU and RTU schemes offer early access opportunities for patients who are in need of medicines that are going through authorization in France. The scheme has so far allowed for rapid access to targeted therapies, immunotherapy, and cell and gene therapies, which have prolonged patient survival or offered a cure for certain serious illness such as leukemia and lymphoma.

The systems have been in place since 1994, with various patient access options such as nominative ATU (nATU) or, more frequently, cohort ATU (cATU). These types of authorization inevitably require follow-up and data collection. Additionally, manufacturers must then submit a market authorization (MA) application within a pre-determined period.

The French alternative reimbursement pathway is currently divided into six systems, but under the reforms the methods will be combined, and just two new mechanisms will be introduced:

- Early access authorization (EAA)
- Compassionate use (CU)

Both will come into force on a date to be determined by decree, but no later than July 1 2021.

Early Access Authorization

The new EAA system will be used primarily for innovative medicines and will be subject to the relevant company's commitment to apply for an MA or for registration on a reimbursement list within a specific timeline.

To be granted an EAA under the new system, a therapy or product must meet the following criteria:

- Absence of an appropriate treatment
- Impossibility to delay the treatment
- Strong presumption of efficacy and safety of the medicine
- Presumed innovative nature of the medicine

France's National Authority for Health (HAS) will act as the competent authority undertaking the assessments, but in the event of medicines that do not have an MA, the French National Agency for the Safety of Health Products (ANSM) will also be required to give an opinion. This change ultimately gives HAS more decision-making power toward manufacturers.

Free and unilateral price setting will henceforth be decided by the relevant pharmaceutical company for submission. Additionally, a mechanism of rebates paid by the company is maintained but will be simplified compared to the ATU system. For example, if the final negotiated price is lower than the price set during the EAA talks, the drugmaker will be required to pay back the difference.

Compassionate Use

The CU pathway will instead be used for certain medicines in specific therapeutic indications and for which, subject to exceptions, no development process is contemplated.

The authorization will be given on the following terms:

- The absence of appropriate treatment to medicines that,
- Subject to exceptions, are not subject to research involving the human person for commercial purposes and
- For which efficacy and safety are presumed to be favorable

Once these criteria have been met, there are two available pathways for the product to follow to gain patient access.

The compassionate access authorization: Upon the request of the prescribing physician, ANSM may authorize the use of a medicine that does not have an MA for the treatment of a serious, rare or incapacitating disease for a named patient;

The compassionate prescription framework: ANSM may establish, on its own initiative or upon the request of a minister, a compassionate prescription framework for a medicine that has an MA in other indications, in order to secure a prescription that does not comply with this authorization.

If the therapy is not yet covered by the French reimbursement system, it will be covered on the basis of the price set freely and unilaterally by the pharmaceutical company that submitted the application or on the basis of an annual flat rate per patient set by the decree.

Additionally, a limit on the total number of CAP requests for the nATUs per product has been introduced. However, if this number is reached, the company will be given the option to file an application for an EAA.

PLFSS

The PLFSS published on December 14, 2020, first penciled in the upcoming changes to the system.

Following the implementation date of July 1, 2021, ATUs with an expiry date after this date will not be eligible for renewal and will have to reapply.

The law ultimately sets the bar for evidence requirements higher than it previously was, both in terms of quality and quantity, potentially leading to a lower number of products being approved through these mechanisms in the future. However, this has yet to be seen.

According to the official text of the PLFSS, the new measures will help create a more cohesive system that entails:

- Rapid access for patients to drugs in advance (although upstream of common law) in a secure environment for use outside the usual,
- Marketing authorization and paid for by health insurance,
- Readability for prescribers,
- Attractiveness and predictability for companies with innovative drugs, and
- Financial sustainability for health insurance

The upheaval of the existing system aims to "simplify demands" as well as "harmonize procedures" according to the document.

The processes currently in use have been deemed overly complex in the past, leading French MPs to decide on replacing the schemes with newer, more streamlined systems. On top of the complexity, MPs cited a lack of readability for all stakeholders as a reason for the reforms.

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IPT for Talzenna First With Economic Evaluation Under REvalMed

Date: June 29, 2021 | Country: SPAIN | Region: EUROPE | Type: HTA | Keywords: #economicevaluation #halaven #lynparza #pfizer #revalmed #therapeuticpositioningreport

PRICENTRIC BRIEF:

- In Spain, REvalMed's Coordination Group has published its first Therapeutic Positioning Report (IPT) with economic evaluation for Pfizer's Talzenna (talazoparib) in adults with advanced or metastatic HER-2 negative breast cancer with BRCA 1/2 mutations
- The IPT notes, "If we apply the 15% discount from Lynparza and we apply it to both drugs, according to the base case, the relation to Halaven is 3.772 times higher. Applying 35% of a discount, according to a sensitivity analysis, the ratio against Halaven remains very high, 2.88 times higher"
- 63 IPTs have been so far adopted, with 32 in Phase 1 (undergoing expert opinion from stakeholders) and 31 in Phase 2 (undergoing review by REvalMed's therapeutic and economic evaluators), and 13 are being developed with economic evaluation

THE DETAILS

MADRID, Spain – In Spain, REvalMed's Coordination Group has published its first Therapeutic Positioning Report (IPT) with economic evaluation for Pfizer's Talzenna (talazoparib) in adults with advanced or metastatic HER-2 negative breast cancer with BRCA 1/2 mutations. Notably, the IPT includes a cost-utility analysis and budget impact analysis.

Talzenna is approved for patients with advanced/metastatic HER2-negative BRCA-mutated breast cancer who have received anthracyclines and/or taxanes in an advanced/metastatic setting or neo/adjuvant, or who are not candidates to receive them. HR+ patients must have received an endocrine therapy, with or without CDK4/6 inhibitors (palbociclib, ribociclib, abemaciclib).

The design and structure of the pharmacoeconomic model has been made—a cost-utility analysis was carried out based on a partitioned survival model with three mutually exclusive health states: progression-free (starting state), progression, and death (final state), from the perspective of the national health system (SNS).

Therapeutic Positioning

The assessment takes into account the EMBRACA study, a Phase 3 clinical trial to study the efficacy of Talzenna.

There is no data on Talzenna in patients who are candidates for curative therapy. Nor has Talzenna been compared to anthracyclines or taxanes in patients who are eligible to receive them. In HR+ previously treated patients who have not yet exhausted hormone therapy, Talzenna has not be compared with endocrine therapy, combined or not. Therefore, Talzenna cannot replace these common therapies in these situations.

Talzenna is a similar option to capecitabine, gemcitabine, or vinorelbine for patients with advanced breast cancer who are not candidates for curative therapy; metastatic, HER2-, with BRCA 1/2 mutation who are not candidates for anthracyclines or taxanes, who have not received platinum therapy or progressed after more than six months after the last dose; and HR+ patients who have previously exhausted endocrine therapy. The report notes that Halaven (eribulin) is positioned in a later line after capecitabine.

Economic Evaluation

As the evaluation of Talzenna was being carried out, the drug was supplied free of charge under the Medicines in Special Situations scheme, noted Diariofarma.

Economic analysis shows that since Talzenna can "hardly compete" with capecitabine, the most used agent in the scenario, it would be employed in a later line, as an alternative to Halaven (or the other agents). In this situation, it would be an equivalent therapeutic alternative to AstraZeneca's Lynparza (olaparib), which underwent a similar trial, does not present differences in progression-free survival (PFS) compared in an indirect comparison with Talzenna, and has a similar toxicity profile.

Lynparza, an equivalent therapeutic alternative, a cost-comparison analysis would be carried out, which has not been developed since there is still no price available for any of them in this indication, as indicated in the IPT.

IPT Notes that "if we apply the 15% discount from olaparib and we apply it to both drugs, according to the base case, the relation to Halaven is 3.772 times higher. Applying 35% discount, according to a sensitivity analysis, the ratio against Halaven remains very high, 2.88 times higher."

Impact and Future of REvalMed

REvalMed oversees the inclusion of economic evaluations in Spain's IPTs, which will now be fundamental in pricing and reimbursement negotiations to guide better decision-making.

According to Diariofarma, 63 IPTs have been so far adopted, with 32 in Phase 1 (undergoing expert opinion from stakeholders) and 31 in Phase 2 (undergoing review by REvalMed's therapeutic and economic evaluators), and 13 are being developed with economic evaluation. Moreover, by utilizing a REvalMed-specific matrix to pinpoint drugs for evaluation, 73 medicines that received a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) have been prioritized for assessment.

Bill Regulating Off-Label Use of Cancer, Orphan Drugs for Children Passes First Reading in Russia State Duma

Date: June 21, 2021 | Country: RUSSIA | Region: ASIA & SOUTH PACIFIC, EUROPE | Keywords: #offlabeluse #oncology #pediatric #raredisease

PRICENTRIC BRIEF:

- A bill from Irina Yarovaya, Deputy Chair of the State Duma, that would regulate the off-label use of drugs for treating children with oncological and hematological diseases has passed its first reading in Russia's State Duma
- The bill provides a mechanism for federal children's cancer centers to formulate a list of effectively used off-label drugs to be sent to the Ministry of Health with recommendations on their inclusion in clinical practice, removes uncertainty surrounding payment for these drugs through compulsory medical insurance and in the provision of high-tech care, and seeks to ensure continuity of treatment for a disease that arose in childhood when the child turns 18, allowing their treatment to continue where it began (in a children's center)
- "According to the bill, off-label drugs that are already included in clinical guidelines or standards for the provision of medical care can be used to cure children. Thus, off-label drugs acquire a legal status for their use within the compulsory medical insurance and VMP," said Yarovaya

THE DETAILS

MOSCOW, Russia – A bill from Irina Yarovaya, Deputy Chair of the State Duma, that would regulate the off-label use of drugs for treating children with oncological and hematological diseases has passed its first reading in Russia's State Duma.

Yarovaya stated, "Today, most of the instructions on the use of anticancer drugs in the world do not contain indications of the possibility of their use in relation to children, that is, in fact, the treatment of children with cancer, rheumatological diseases, diseases of the blood, nervous system and a number of others today is based solely on the so-called drugs outside the instructions by application. Thus, without the use of off-label drugs, it is impossible to cure children with severe chronic diseases."

The bill provides a mechanism for federal children's cancer centers to formulate a list of effectively used off-label

drugs to be sent to the Ministry of Health with recommendations on their inclusion in clinical practice. The bill also removes uncertainty surrounding payment for these drugs through compulsory medical insurance and in the provision of high-tech care.

Moreover, the bill seeks to ensure continuity of treatment for a disease that arose in childhood when the child turns 18, allowing their treatment to continue where it began, (in a children's center), as long as a medical commission decides it's the best course of action.

Before starting off-label drug use, the physician must inform the patient or their legal representative about the drug, including the safety and expected effect of treatment, as well as any risk.

"According to the bill, off-label drugs that are already included in clinical guidelines or standards for the provision of medical care can be used to cure children. Thus, off-label drugs acquire a legal status for their use within the compulsory medical insurance and VMP," said Yarovaya.

Nizhny Novgorod Pharmacies Pilot Free Medicine for Outpatient Cardiovascular Patients

Date: June 10, 2021 | Country: RUSSIA | Region: ASIA & SOUTH PACIFIC, EUROPE | Type: Pricing & Reimbursement | Keywords: #cardiovascular #copayment #eprescription #outpatientcare #pharmacy #prescribing

PRICENTRIC BRIEF:

- A pilot project has been launched in a number of hospitals in Nizhny Novgorod to provide medicines for free to patients who have recently suffered acute cerebrovascular accident or myocardial infarction, or those who have undergone coronary artery bypass grafting, angioplasty of coronary arteries with stenting, and catheter ablation for cardiovascular disease
- The pilot targets patients undergoing treatment for cardiovascular pathologies who have been discharged from a cardiovascular center and aims to provide them preferential drugs for up to six months
- The Nizhny Novgorod Regional Pharmacy has installed the proper software, organized a prescription center and set up a workplace for dispensing prescriptions for these preferential drugs—the system is updated daily and allows orders to be made for a specific patients in the required quantity and dosage, thereby saving patients trips to the pharmacy through electronic recordkeeping

THE DETAILS

NIZHNY NOVGOROD, Russia – A pilot project has been launched in a number of hospitals in Nizhny Novgorod to provide medicines for free to patients who have recently suffered acute cerebrovascular accident or myocardial infarction, or those who have undergone coronary artery bypass grafting, angioplasty of coronary arteries with stenting, and catheter ablation for cardiovascular disease.

The pilot targets patients undergoing treatment for cardiovascular pathologies who have been discharged from a cardiovascular center and aims to provide them preferential drugs for up to six months.

The Nizhny Novgorod Regional Pharmacy has installed the proper software, organized a prescription center and set up a workplace for dispensing prescriptions for these preferential drugs—the system is updated daily and allows orders to be made for a specific patients in the required quantity and dosage. Already, the regional pharmacy has sent a batch of preferential drugs and the first patients discharged from the region's vascular center received them upon discharge for a period of one to six months.

Head of IT and Software Development Alexander Kulakov said that this approach is "essentially beneficial to everyone: supplying organizations, regulatory authorities and of course, first of all, cardiovascular patients themselves." Kulakov elaborated that patients no longer need to rely on paper prescriptions nor frequent pharmacy trips, as all patient information is sent

immediately to the pharmacy, and the software tracks "both the nomenclature and dosage."

With funding from both the federal and regional budget, the Ministry of Health of Nizhny Novgorod initiated the pilot to strengthen control over the provision of subsidized medicines for citizens with cardiovascular disease who are under dispensary observation.

Russia Changes Requirements for Patent Extensions to Facilitate Easier Market Access for Generics

Date: June 9, 2021 | Country: RUSSIA | Region: ASIA & SOUTH PACIFIC, EUROPE | Type: Regulation | Keywords: #affordability #drugformulation #generic #marketaccess #patent #patentextension

PRICENTRIC BRIEF:

- The Ministry of Economic Development of Russia has changed the requirements for patent extensions for medicines to facilitate swifter and easier access for more affordable generics on the market
- As of yesterday, June 8, 2021, a manufacturer will only be able to extend a patent if significant changes are made to the formula of a medicine and "not on a formal basis"
- As such, Russia is nixing its previous rule that allowed patent extensions when a minor modification/improvement to a drug's formulation is made, extended patent terms "indefinitely" and prevented generics from entering the market

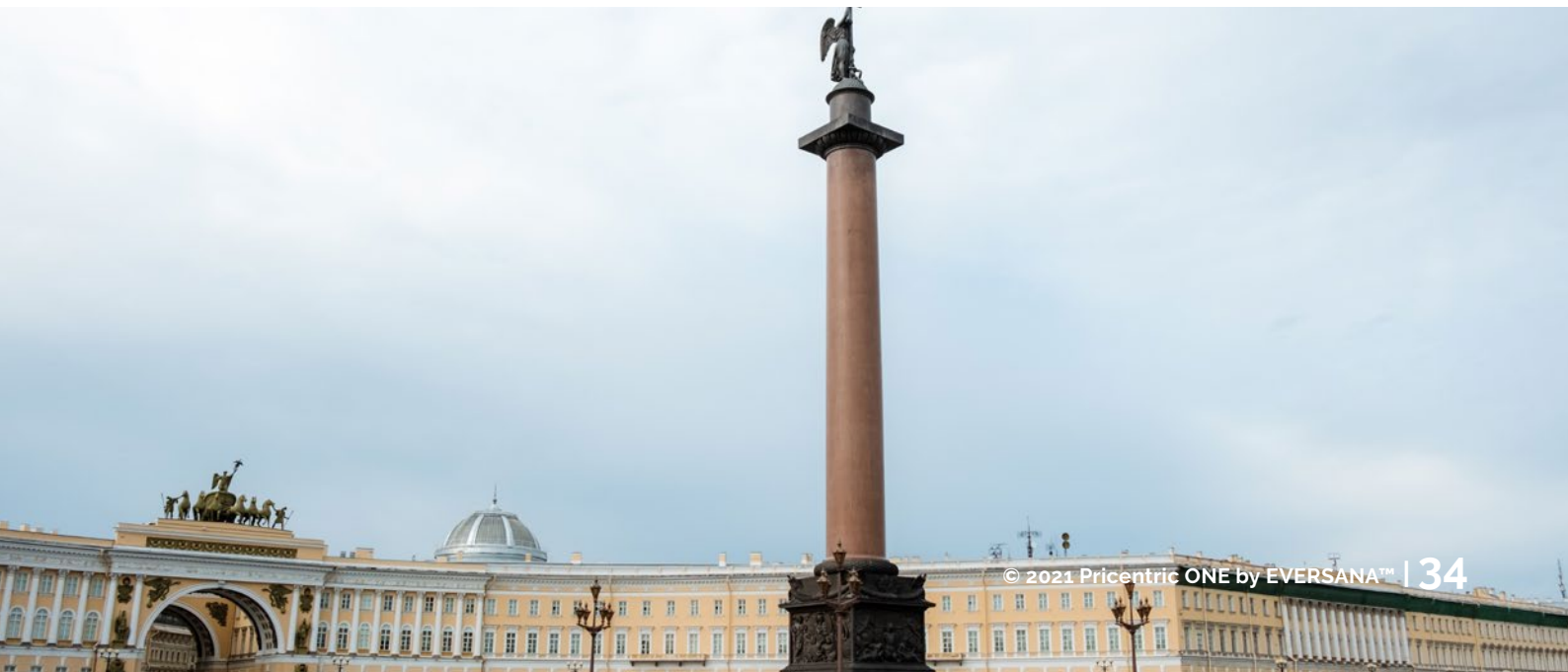
THE DETAILS

MOSCOW, Russia – The Ministry of Economic Development of Russia has changed the requirements for patent extensions for medicines to facilitate swifter and easier access for more affordable generics on the market.

Henceforth, a manufacturer will be able to extend a patent only if significant changes are made to the formula of a medicine and "not on a formal basis."

As such, Russia is nixing its previous rule that allowed patent extensions when a minor modification/improvement to a drug's formulation is made, extended patent terms "indefinitely" and prevented generics from entering the market—or "renewal strategies," according to Vladislav Fedulov, Deputy Minister of Economic Development.

The Ministry of Justice has registered the order and it came into force June 8, 2021.



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United States Issues Policy Recommendations to Address Pharmaceutical Supply Chain

Date: June 10, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Regulation | Keywords: #access #api #aspr #covid19 #domesticproduction #drugshortage #fda #hhs #incentive #supplychain

PRICENTRIC BRIEF:

- The United States White House, Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Food and Drug Administration (FDA) have issued a series of policy recommendations addressing vulnerabilities in U.S. pharmaceutical supply chains exposed by the COVID-19 pandemic
- The report from these agencies and governing body centers on four pillars to secure the supply chain: 1) boosting local production and fostering international cooperation, 2) promoting research and development (R&D) that establishes innovative manufacturing processes and production technologies to strengthen supply chain resilience; 3) creating robust quality management maturity to ensure consistent and reliable drug manufacturing and quality performance; and 4) leveraging data to improve supply chain resilience
- HHS is committing approximately $60 million to develop novel platform technologies to increase the U.S.'s domestic manufacturing capacity for API: U.S. agencies and the private sector are collaborating to help provide Americans with timely access to pharmaceuticals: and the report calls for incentives for detecting and mitigating supply chain issues, as well as new initiatives to collect supply chain-specific data that encourage the private sector to improve its resiliency and reduce shortages

THE DETAILS

WASHINGTON, D.C., United States – The United States White House, Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Food and Drug Administration (FDA) have issued a series of policy recommendations addressing vulnerabilities in U.S. pharmaceutical supply chains exposed by the COVID-19 pandemic.

In February 2021, U.S. President Joe Biden issued Executive Order (E.O.) 14017 calling for an evaluation of critical supply chains within 100 days, with a strategy to make sure they're secure. The report, which serves as a follow-up to the E.O., highlighted the U.S.'s increasing reliance on foreign manufacturers for medicines, active pharmaceutical ingredients (APIs), and key starting materials (KSMs).

The report from these agencies and governing body centers on four pillars to secure the supply chain: 1) boosting local production and fostering international cooperation, 2) promoting research and development (R&D) that establishes innovative manufacturing processes and production technologies to strengthen supply chain resilience; 3) creating robust quality management maturity to ensure consistent and reliable drug manufacturing and quality performance; and 4) leveraging data to improve supply chain resilience.

HHS is committing approximately $60 million from the Defense Production Act appropriation in the American Rescue Plan to develop novel platform technologies to increase the U.S.'s domestic manufacturing capacity for API. Further, U.S. agencies and the private sector are collaborating to help provide Americans with timely access to pharmaceuticals, and the report calls for incentives for detecting and mitigating supply chain issues, as well as new initiatives to collect supply chain-specific data that encourage the private sector to improve its resiliency and reduce shortages.

PASTEUR Act Proposes Subscription Payment Model to Encourage Novel Antibiotic Development

Date: June 18, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Editor's Choice, Policy | Keywords: #antimicrobialresistance #cdc #criticalneedantimicrobial #hhs #incentive #pasteuract #subscriptionpaymentmodel #supplycontract

PRICENTRIC BRIEF:

- United States Senators Michael Bennet (D-CO) and Todd Young (R-IN) and Representatives Mike Doyle (D-PA) and Drew Ferguson (R-GA) have reintroduced the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act to incentivize development of novel antibiotics and introduce a subscription-style model of payment for them
- Whereas current government contracts with manufacturers base payment on value, the PASTEUR Act would establish a subscription-style payment model that offers antibiotic developers an upfront payment for access to their antibiotics, with contracts ranging from $750 million to $3 billion and lasting either 10 years or through patent exclusivity
- With a total of $11 billion in funding marked for the next 10 years, the Department of Health and Human Services (HHS) Secretary would appoint a new "Committee on Critical Need Antimicrobials" and "Critical Need Advisory Group" to identify infections to target antimicrobial development, select an office to manage subscription contracts, and develop regulations and guidance determining the monetary valuations and terms of these contracts–Antimicrobial developers can apply for "Critical Need Antimicrobial" Designation, and HHS will evaluate and determine the drug's subscription contract eligibility and value

THE DETAILS

WASHINGTON, D.C., United States – United States Senators Michael Bennet (D-CO) and Todd Young (R-IN) and Representatives Mike Doyle (D-PA) and Drew Ferguson (R-GA) have reintroduced the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act to incentivize development of novel antibiotics and introduce a subscription-style model of payment for them.

Under the U.S. National Action Plan for Combatting Antibiotic-Resistant Bacteria of March 2015, federal agencies were directed to accelerate the government's response to antibiotic resistance by increasing and incentivizing the development of innovative antimicrobial drugs, but "market failures" led to many innovative companies filing for bankruptcy and stopping production.

Whereas current government contracts with manufacturers base payment on value, the PASTEUR Act would establish a subscription-style payment model that offers antibiotic developers an upfront payment for access to their antibiotics, with contracts ranging from $750 million to $3 billion and lasting either 10 years or through patent exclusivity.

With a total of $11 billion in funding marked for the next 10 years, the Department of Health and Human Services (HHS) Secretary would appoint a new "Committee on Critical Need Antimicrobials" and "Critical Need Advisory Group" to identify infections to target antimicrobial development, select an office to manage subscription contracts, and develop regulations and guidance determining the monetary valuations and terms of these contracts.

Antimicrobial developers can apply for "Critical Need Antimicrobial" Designation, and HHS will evaluate and determine the drug's subscription contract eligibility and value. The contract value will be determined by evidence-based preferred drug characteristics to incentivize development and be delinked, with payments adjusted down by any amount federal health programs pay for the drug.

Developers can apply to HHS for a subscription at or within five years following Food and Drug Administration (FDA) approval; however, during the transition period, HHS may use funding to enter smaller contracts, as long as these include terms of participation, appropriate use strategies, FDA-required post-marketing studies and a reliable supply chain. In general, once contracts are due to expire, HHS and the manufacturer can negotiate smaller, secondary contracts to extend the subscription or adjust the value.

Patients covered by federal insurance will receive these drugs at no cost. HHS and the Centers for Disease Control and Prevention (CDC) will use health surveillance systems to collect relevant data on antibiotic use, with the CDC conducting an annual report for Congress. Further, within six years, the Government Accountability Office will conduct a study on the efficacy of this program.

Florida Requests Federal Approval of Canadian Prescription Drug Importation Plan

Date: June 9, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy | Keywords: #ahca #amicusbrief #fda #hhs #imports #medicare #prescriptiondrugimportplan #regulation

PRICENTRIC BRIEF:

- Florida Governor Ron DeSantis has called on the Biden Administration to approve the Section 804 Importation Proposal (SIP) of the State of Florida's Canadian Prescription Drug Importation Plan, which was passed by Florida's legislative body in November 2019, and the Administration is in agreement
- Industry blocs have filed a suit challenging one of former President Donald Trump's four Executive Orders from July 2020 that sought to allow then Department of Health and Human Services (HHS) Secretary Alex Azar to investigate the possibility of importing prescription drugs from Canada, and Biden's Administration has even filed a motion in federal court to dismiss the case
- According to DeSantis, the Florida Agency for Health Care Administration (AHCA) has filed an Amicus brief in support of the HHS final rule and requested the Courts dismiss the plaintiff's claims because they "have not established standing"—DeSantis further explained that Florida is well-prepared to ensure the quality and safety of imported drugs, and AHCA and its partners are ready to commence importation, having already secured a vendor (LifeScience Logistics, LLC) to assist in the administration of the program

THE DETAILS

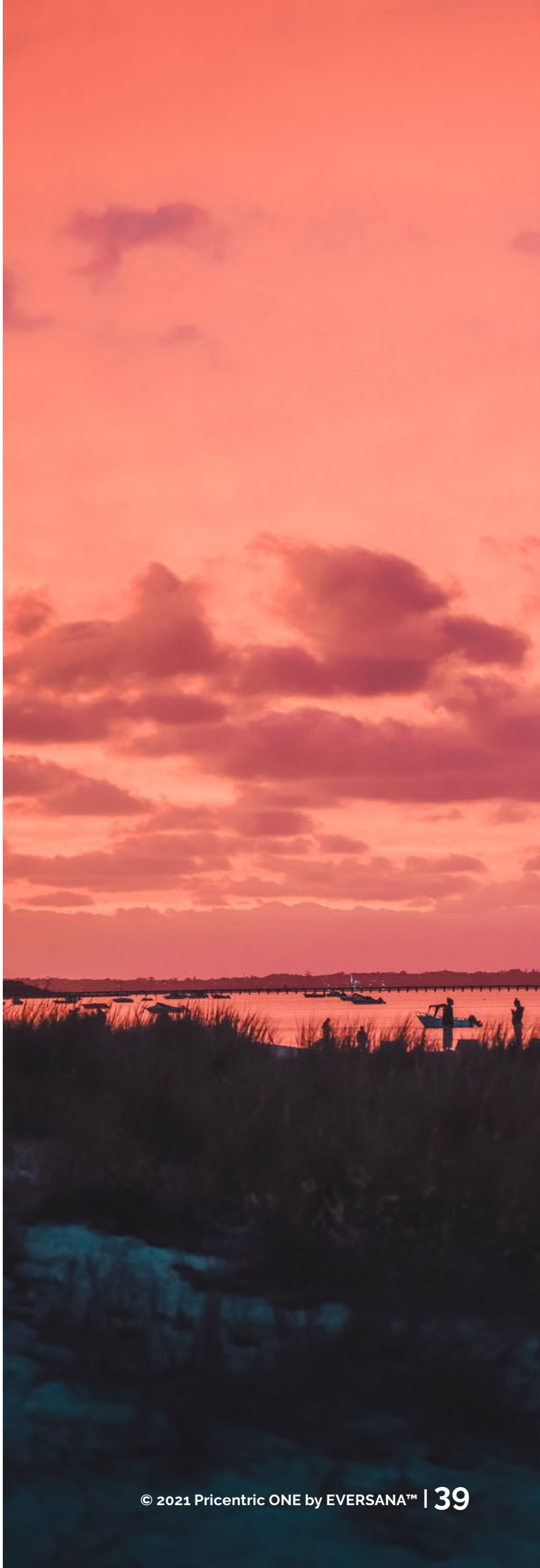
TALLAHASSEE, Florida – Florida Governor Ron DeSantis has called on the Biden Administration to approve the Section 804 Importation Proposal (SIP) of the State of Florida's Canadian Prescription Drug Importation Plan, which was passed by Florida's legislative body in November 2019, and the Administration is in agreement.

One of former President Donald Trump's four Executive Orders from July 2020 sought to allow then Department of Health and Human Services (HHS) Secretary Alex Azar investigate the possibility of importing prescription drugs from Canada. The plan from the Food and Drug Administration (FDA) and HHS was formed in collaboration with Florida, the state's 2019 importation concept directly influencing the federal initiative. Although Azar accomplished these preliminary steps, following the orders of Congress, industry blocs have filed a suit challenging the final rule.

According to DeSantis, the Florida Agency for Health Care Administration (AHCA) has filed an Amicus brief in support of the HHS final rule and requested the courts dismiss the plaintiff's claims because they "have not established standing." DeSantis further explained that Florida is well-prepared to ensure the quality and safety of imported drugs and has solid regulatory framework already in place. Biden's Administration has even filed a motion in federal court to dismiss the case.

AHCA and its partners are ready to commence importation, having already secured a vendor (LifeScience Logistics, LLC) to assist in the administration of the program—namely, negotiating with Canadian prescription drug manufacturers and developing an online portal for state agencies to order drugs.

Initially, the program will cover a small number of drug classes—asthma, COPD, diabetes, HIV/AIDS and mental illness—for patients under the care of select government agencies before it is expanded to include Medicare beneficiaries across Florida. DeSantis said that the plan "will improve access to essential medications for our most vulnerable citizens and potentially save the state between $80 to $150 million in the first year alone."



Maine Senate Approves 5 Bills Targeting Drug Price Increases, Price Transparency

Date: June 22, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy, Price Changes, Pricing & Reimbursement | Keywords: #generic #insulin #mainehealthdataorganization #makinghealthcareworkformaine #offpatent #pricecap #priceincreases #pricetransparency

PRICENTRIC BRIEF:

- The Maine Senate has passed the "Making Health Care Work for Maine" package of bills put forth by Senator Troy Jackson targeting health care spending, prescription drug price increases, and prescription drug transparency

- Of note, LD 1117, "An Act to Prevent Excessive Prices for Prescription Drugs" would prohibit excessive price increases for generic and off-patent prescription drugs sold in Maine, LD 686, "An Act to Increase Prescription Drug Pricing Transparency," would allow Maine Health Data Organization (MHDO) to make accessible to the public information collected from drug manufacturers, and LD 657, "An Act to Protect Maine Consumers from Unsupported Price Increases on Prescription Medicines by Creating an Independent Review Process" would prohibit pharmaceutical companies from raising the cost of their drugs when there is no evidence to support the increase

- An emergency 30-day supply of insulin would be made available to eligible Mainers at any pharmacy for less than $35 under LD 673, "An Act to Create the Insulin Safety Net Program," and it would be funded by insulin manufacturers, who would be required to register with the state

THE DETAILS

AUGUSTA, ME, United States – The Maine Senate has passed the "Making Health Care Work for Maine" package of bills put forth by Senator Troy Jackson targeting health care spending, prescription drug price increases, and prescription drug transparency.

The first bill, LD 120 "An Act to Lower Health Care Costs through the Establishment of the Office of Affordable Health Care," would establish the Office of Affordable Health Care to rein in health care spending and improve access by analyzing Maine's health data and making evidence-based policy recommendations.

LD 1117, "An Act to Prevent Excessive Prices for Prescription Drugs" would prohibit excessive price increases for generic and off-patent prescription drugs sold in Maine, requiring Maine Health Data Organization (MHDO) to notify the Attorney General of any excessive price increases for investigation.

Under LD 686, "An Act to Increase Prescription Drug Pricing Transparency," MHDO can make accessible to the public information collected from drug manufacturers.

An emergency 30-day supply of insulin would be made available to eligible Mainers at any pharmacy for less than $35 under LD 673, "An Act to Create the Insulin Safety Net Program," and it would be funded by insulin manufacturers, who would be required to register with the state.

Finally, LD 657, "An Act to Protect Maine Consumers from Unsupported Price Increases on Prescription Medicines by Creating an Independent Review Process" would prohibit pharmaceutical companies from raising the cost of their drugs when there is no evidence to support the increase. Any drug company found in violation would be hit with a fine by the Maine State Treasurer, based on information provided by the Prescription Drug Affordability Board.

The House will vote on these five bills next.

Colorado Legislature Passes Another Bill Aimed at Lowering Prescription Drug Costs

Date: June 14, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Policy, Pricing & Reimbursement | Keywords: #affordability #pharmacy #prescriptiondrug #prescriptiondrugaffordabilityreviewboard #priceceiling #pricingcontrol #sb21-123 #sb21-175

PRICENTRIC BRIEF:

- The Colorado Legislature recently passed SB21-175, which directs Colorado's Prescription Drug Affordability Review Board to review the affordability of certain prescription drugs and establish payment limits for these drugs, and entities will be prohibited from purchasing or reimbursing any drug for distribution in Colorado at an amount above the fixed payment limit
- The board would be permitted to set limits for 12 drugs per year; however, the board can still review other drugs and make recommendations
- Colorado Governor Jared Polis supports the bill and will likely sign it into law, as it aligns with the Governor's recent decision to sign into law SB21-123, expanding the state's Canadian Prescription Drug Import Plan to allow the import of prescription drugs from suppliers from nations other than Canada

THE DETAILS

DENVER, Colorado – On June 8th, 2021, the Colorado Legislature passed SB21-175, which directs Colorado's Prescription Drug Affordability Review Board to review the affordability of certain prescription drugs and establish upper limit payments for these drugs, and entities will be prohibited from purchasing or reimbursing any drug for distribution in Colorado at an amount above the fixed upper payment limit.

Starting April 1, 2022, the board would be able to set upper payment limits for 12 drugs per year for a three-year period; however, the board can still review other drugs and make recommendations. The review can be triggered by any of the following: WAC increase by more than 10% over a one-year period for a one-year supply, an initial WAC of more than $30,000 per year or a biosimilar that is not at least 15% lower than its reference product. The bill also outlines specific triggers for generic drug costs as well. Coloradans can also request the board to review certain prescriptions.

The bill was first introduced in March by Democratic Senators along with SB21-123. Colorado Governor Jared Polis supports SB21-175 and will likely sign it into law. In April 2021,Governor Polis also signed SB21-123 into law, expanding Colorado's prescription drug importation program to allow the state to import medicines from countries beyond Canada, such as Japan, France and Australia.

United States Buys 200 Million Additional Doses of Moderna COVID-19 Vaccine

Date: June 17, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Other | Keywords: #bla #covid19 #emergencyuseauthorization #moderna #vaccine.purchaseagreement

PRICENTRIC BRIEF:

- The United States Government has purchased an additional 200 million doses of Moderna's COVID-19 vaccine, which includes an option to purchase other COVID-19 vaccine candidates from Moderna's pipeline, bringing the government's confirmed order commitment to 500 million doses
- At the beginning of June, Moderna initiated a rolling submission with the U.S. Food and Drug Administration (FDA) for a Biologics License Application (BLA) seeking approval for its COVID-19 vaccine
- Additionally this June, Moderna filed with the FDA an Emergency Use Authorization (EUA) request for its COVID-19 vaccine in adolescents, based on the Phase 2/3 TeenCOVE study of the vaccine that met its primary immunogenicity endpoint, successfully bridging immune responses to the adult vaccination

THE DETAILS

WASHINGTON, D.C., United States – The United States Government has purchased an additional 200 million doses of Moderna's COVID-19 vaccine, which includes an option to purchase other COVID-19 vaccine candidates from Moderna's pipeline.

Today's announcement brings the U.S. Government's confirmed order commitment to 500 million doses, including 110 million doses expected to be delivered in Q4 of 2021 and 90 million expected in Q1 2022.

Moderna noted that as of June 14, 2021, it has supplied 217 million released doses of its vaccine to the U.S. Government.

Stéphane Bancel, Chief Executive Officer of Moderna, commented, "We appreciate the collaboration with the U.S government for these additional doses of the Moderna COVID-19 vaccine, which could be used for primary vaccination, including of children, or possibly as a booster if that becomes necessary to continue to defeat the pandemic. We remain focused on being proactive as the virus evolves by leveraging the flexibility of our mRNA platform to stay ahead of emerging variants."

At the beginning of June, Moderna initiated a rolling submission with the U.S. Food and Drug Administration (FDA) for a Biologics License Application (BLA) seeking approval for its COVID-19 vaccine. Under the rolling submission, the company will submit data to support the BLA to the FDA on a rolling basis over the coming weeks with a request for a Priority Review. The move makes Moderna the second company in the U.S. to seek a biologics license that will allow it to market the vaccine directly to the public, following Pfizer earlier this year.

Shortly after, Moderna filed with the FDA an Emergency Use Authorization (EUA) request for its COVID-19 vaccine in adolescents, based on the Phase 2/3 TeenCOVE study of the vaccine that met its primary immunogenicity endpoint, successfully bridging immune responses to the adult vaccination.

Senators Crapo, Burr Reintroduce Lower Costs, More Cures Act

Date: June 29, 2021 | Country: UNITED STATES | Region: NORTH AMERICA | Type: Editor's Choice, Policy | Keywords: #biosimilarpartd #hhs #hr19 #hr3 #incentive #insulin #lowercostsmorecuresact #medicare #outofpocketpayment #partb #prescriptiondrug #referencepricing(irp) #transparency

PRICENTRIC BRIEF:

- United States Senator Mike Crapo (R-ID), Ranking Member of the Senate Finance Committee, and Senator Richard Burr (R-NC), Ranking Member of the Senate Health, Education, Labor, and Pensions Committee, have reintroduced S. 3129, the Lower Costs, More Cures Act (LCMCA) aimed at lowering prescription drug prices and boosting transparency in the industry while simultaneously encouraging the development of new cures and treatments
- Taking up the mantle of the House's H.R. 19, which was also first introduced in 2019, LCMCA is being put forth as a "commonsense solution" to bringing down prescription drug pricing "by expanding access to alternative treatments and incentivizing the creation of new cures," according to original co-sponsor of the Act Senator Jim Risch (R-ID)
- Instead of trying to leverage the negotiating power of Medicare and utilizing a form of reference pricing, LCMCA focuses efforts on resetting Part B reimbursement and proposes, like H.R. 3, a Part D redesign

THE DETAILS

WASHINGTON, D.C., United States – United States Senator Mike Crapo (R-ID), Ranking Member of the Senate Finance Committee, and Senator Richard Burr (R-NC), Ranking Member of the Senate Health, Education, Labor, and Pensions Committee, have reintroduced S. 3129, the Lower Costs, More Cures Act (LCMCA) aimed at lowering prescription drug prices and boosting transparency in the industry, while simultaneously encouraging the development of new cures and treatments. The bill will take up the mantle of the House's H.R. 19, which was also first introduced in 2019.

As outlined by Senator Crapo, LCMCA (S 3129) would:

- Modernize payments for drugs delivered in the doctor's office under Medicare Part B by establishing an add-on payment for drugs;
- Incentivize lower-cost alternatives or biosimilars;
- Establish an annual out-of-pocket cap of $3,100 for Medicare Part D enrollees and allow certain patients to pay in monthly installments;
- Decrease beneficiary cost sharing in the initial coverage phase from 25% to 15% of costs before the out-of-pocket cap is reached;
- Allow prescription drug plan sponsors to offer, at minimum, up to four Part D plans per region, spurring competition and innovation;
- Make permanent the Center for Medicare and Medicaid Innovation model (Senior Savings) that enables Part D enrollees taking insulin to limit out-of-pocket costs to $35;
- Allow state Medicaid programs to enter into outcomes-based agreements to pay for life-saving gene therapy treatments;
- Provide the HHS Secretary with the authority to require drug manufacturers to provide pricing information on all direct-to-consumer advertising;
- Extends IRS classification of insulin and other treatments for chronic conditions as preventive care so that high-deductible health plans can cover costs before the patient reaches the deductible; and
- Create a trade negotiator solely dedicated to putting American patients first in government trade negotiations related to medicines in order to prevent foreign free-loading off America's investment.

The Act is being put forth as a "commonsense solution" to bringing down prescription drug pricing "by expanding access to alternative treatments and incentivizing the creation of new cures," according to the original co-sponsor of the Act Senator Jim Risch (R-ID). Risch further added that "the bill increases drug pricing transparency and caps patients' out-of-pocket costs for life-saving medication."

Backed by a coalition of Republicans, LCMCA is being presented as alternative to the Elijah Cummings Lower Drug Costs Now Act (H.R. 3), which has been promoted

by U.S. Speaker of the House Nancy Pelosi. Under H.R. 3, Medicare—specifically, the Secretary of the Department of Health and Human Services (HHS)—would be empowered to negotiate drug prices directly with pharmaceutical companies, and these negotiated drug prices would be extended to commercial business as well. A maximum price would be applied, based on the drug's average price (dubbed the "Average International Market (AIM) price") among Australia, Canada, France, Germany, Japan and the United Kingdom. The Lower Costs, More Cures Act stops short of empowering Medicare to negotiate prices.

Instead, it focuses efforts on resetting Part B reimbursement and proposes, like H.R. 3, a Part D redesign. While S 3129 sets the OOPC cap at $3,100, H.R. 3 sets it at $2,000. S 3129 increases payer responsibility in the initial coverage phase to 75% with a 10% commitment from biopharmaceutical companies, while H.R. 3 continues the ICP payer coverage of 25%. In the catastrophic phase, S 3129 continues the 10% rebate from biopharma, while H.R. 3 shifts more responsibility to 30% from biopharma.

	S 3129	**H.R. 3**
OOPC cap	$2,000	$3,100
ICP responsibility	75% payer 10% biopharma 15% beneficiary	65% payer 10% biopharma 25% beneficiary
Catastrophic coverage responsibility	70% payer 10% biopharma 20% Medicare	50% payer 30% biopharma 20% Medicare

China's NHSA Seeks Feedback on Working Plan for 2021 NRDL Adjustment

Date: June 11, 2021 | Country: CHINA | Region: ASIA & SOUTH PACIFIC | Type: Pricing & Reimbursement | Keywords: #basicmedicalinsurance #covid19 #generic #nedl #nhsa #nmpa #nrdl

PRICENTRIC BRIEF:

- The National Healthcare Security Administration (NHSA) of China is currently soliciting feedback on its "Working Plan for 2021 National Medical Insurance Drug List Adjustment" and "2021 National Medical Insurance Drug List Adjustment Report Guidelines," two documents outlining the shape of China's 2021 adjustments to the National Reimbursement Drug List (NRDL)
- To be included in the scope of the 2021 NRDL, western medicines and traditional Chinese medicines (TCMs) must meet the provisions of Articles 7 and 8 of the "Interim Measures for the Administration of Drugs for Basic Medical Insurance," and can be either new generic drugs approved for marketing or drugs with approved major changes in indications or functions from January 1, 2016 to June 30, 2021; respiratory drugs for COVID-19; or drugs included in the 2018 Edition of the National Essential Drug List (NEDL)
- The documents call for an adjustment to the scope of payment standards for drugs, as well, specifically for drugs included in the NRDL through negotiation that are still within agreement terms but need their payment standards rehashed in accordance with agreements; based on manufacturer applications, drugs included in the NRDL through negotiation that are deemed by expert review to need payment scope limitation adjustment; and compared with drug products in the same therapeutic category, drug products with higher prices or expenditures and have recently consumed substantial BMI funds

THE DETAILS

BEIJING, China – The National Healthcare Security Administration (NHSA) of China is currently soliciting feedback on its "Working Plan for 2021 National Medical Insurance Drug List Adjustment" and "2021 National Medical Insurance Drug List Adjustment Report Guidelines," two documents outlining the shape of China's 2021 adjustments to the National Reimbursement Drug List (NRDL).

The NRDL adjustment for 2021 is divided into five stages: preparation, declaration, expert review, negotiation and, finally, announcement of results. Adjustments to the 2021 NRDL must consider the functional positioning of basic medical insurance (BMI), clinical need for drugs and the affordability of funds.

To be included in the scope of the 2021 NRDL, western medicines and traditional Chinese medicines (TCMs) must meet the provisions of Articles 7 and 8 of the "Interim Measures for the Administration of Drugs for Basic Medical Insurance" and can be either new generic drugs approved for marketing or drugs with approved major changes in indications or functions from January 1, 2016 to June 30, 2021; respiratory drugs for COVID-19; or drugs included in the 2018 Edition of the National Essential Drug List (NEDL).

The deadline for determining NRDL inclusion of a drug is June 30, 2021.

Drugs whose approvals have been terminated, suspended, or withdrawn by the National Medical Products Administration (NMPA), and those determined to have greater risk than benefit, considering clinical value, adverse reactions, and pharmaco-economics are to be removed from the 2021 NRDL.

The documents call for an adjustment to the scope of payment standards for drugs, as well, specifically for drugs included in the NRDL through negotiation that are still within agreement terms but need their payment standards rehashed in accordance with agreements; based on manufacturer applications, drugs included in the NRDL through negotiation that are deemed by expert review to need payment scope limitation adjustment; and compared with drug products in the same therapeutic category, drug products with higher prices or expenditures and have recently consumed substantial BMI funds.

One-Third of Shanghai Residents Subscribe to Commercial Supplementary Health Insurance Huhuibao

Date: June 16, 2021 | Country: CHINA, CHINA-SHANGHAI | Region: ASIA & SOUTH PACIFIC | Type: Policy | Keywords: #basicmedicalinsurance #chinapacificlifeinsurance #commercialhealthinsurance #hospital #huhuibao #nmpa #oncology #orphandrug #premium #raredisease

PRICENTRIC BRIEF:

- Since Shanghai's commercial supplementary medical insurance coverage Huhuibao launched at the end of April in Shanghai, more than 6.1 million residents have signed up, according to China Pacific Life Insurance, one of nine insurance companies partnered with Shanghai to offer the additional coverage
- A new customized, supplementary medical insurance program available to all people who use Shanghai's current BMI, Huhuibao costs an annual fee of 115 yuan regardless of age, offers medical compensation up to 2.3 million yuan, and covers payments beyond the ambit of the BMI, including for some hospitalization charges and 21 undisclosed but "expensive" medicines for cancer and rare disease, and proton and heavy ion radiation treatments
- To be eligible for Huhuibao, customers must first be using the basic medical insurance (BMI) scheme—Of the 19.1 million who are insured under the scheme, almost a third (6.1 million), many of whom bundled coverage for their family, have purchased Huhuibao

THE DETAILS

SHANGHAI, China – Since Shanghai's commercial supplementary medical insurance coverage Huhuibao launched at the end of April in Shanghai, more than 6.1 million residents have signed up, according to China Pacific Life Insurance, one of nine insurance companies partnered with Shanghai to offer the additional coverage.

To be eligible for Huhuibao, customers must first be using the basic medical insurance (BMI) scheme. Of the 19.1 million who are insured under the scheme, almost a third (6.1 million), many of whom, bundled coverage for their family, have purchased Huhuibao.

A new customized, supplementary medical insurance program available to all people who use Shanghai's current BMI, Huhuibao costs an annual fee of 115 yuan regardless of age, offers medical compensation up to 2.3 million yuan, and covers payments beyond the ambit of the BMI, including for some hospitalization charges and 21 undisclosed but "expensive" medicines for cancer and rare disease and proton and heavy ion radiation treatments.

Although the premium for Huhuibao is higher than what's offered by other commercial health insurance policies in China, it offers medicines that are not yet on the BMI list of approved drugs.

Payments for the first year of Huhuibao run until June 30 and take effect on July 1.

A recent study conducted by Fudan University and Shanghai-based health insurer Shanzhen Haiwei predicted a rise in more diversified, low-cost and inclusive health insurance plans in China this year to make up for the lack of coverage for certain populations in China. The report asserts that coverage will gradually expand from first- and second-tier cities to smaller ones, with the prices of products and scope of protection diversifying.

Overall, the BMI scheme has been tweaked to cover more outpatient medical bills, and a special commercial medical insurance scheme covering 49 imported innovative drugs was recently launched in Hainan's Boao Lecheng International Medical Tourism Pilot Zone to lower costs and boost access for patients.

Low-Cost Supplementary Insurance Plans Launch Across China

Date: June 17, 2021 | Country: CHINA, CHINA-GUANGDONG, CHINA-OTHER PROVINCES, CHINA-SHANGHAI | Region: ASIA & SOUTH PACIFIC | Type: Policy | Keywords: #basicmedicalinsurance #commercialhealthinsurance #huhuibao #huiminbao #oncology #orphandrug #premium #raredisease

PRICENTRIC BRIEF:

- A total of 140 supplementary insurance plans known as Huiminbao have launched across 26 provinces in China, covering more than 30 million people, to fill in gaps between the Basic Medical Insurance (BMI) scheme and commercial critical illness plans
- Huiminbao plans typically offer one price, regardless of the age of the beneficiary, and cover those with pre-existing conditions
- Specifically, low-cost Huiminbao covers high-priced drugs excluded from the ambit of the BMI scheme, including drugs for breast cancer, prostate cancer, melanoma, liver cancer, lung cancer, leukemia, lymphoma, ovarian cancer, giant cell tumor of the bone and multiple myeloma—Further, Huiminbao has expanded to cover medical treatments such as proton and heavy ion therapy related to pneumonia, malignant tumors and rare disease

THE DETAILS

SHANGHAI, China – According to a study by the Insurance Innovation and Investment Research Center of the Fanhai International School of Finance at Fudan University, a total of 140 supplementary insurance plans known as Huiminbao have launched across 26 provinces in China, covering more than 30 million people.

Huiminbao fills in gaps between the Basic Medical Insurance (BMI) scheme and commercial critical illness plans. Specifically, low-cost Huiminbao covers high-priced drugs excluded from the ambit of the BMI scheme, including drugs for breast cancer, prostate cancer, melanoma, liver cancer, lung cancer, leukemia, lymphoma, ovarian cancer, giant cell tumor of the bone and multiple myeloma. Further, Huiminbao has expanded to cover medical treatments such as proton and heavy ion therapy related to pneumonia, malignant tumors and rare disease.

Huiminbao plans typically offer one price, regardless of the age of the beneficiary, and cover those with pre-existing conditions. The annual deductible is around CNY 20,000, and the average single premium is between 20% and 30% of the premium payable.

The first such plan was offered in Shenzhen in 2015, but the program truly took off this year, after the China Banking and Insurance Regulatory Commission (CBIRC) and 13 other agencies released guidance urging commercial insurers to improve their services. Twenty Huiminbao plans have been launched in Jiangsu, 19 in Guangdong, and 16 in Zhejiang.

Supplementary Insurance Plans on the Rise

A recent study conducted by Fudan University and Shanghai-based health insurer Shanzhen Haiwei predicted a rise in more diversified, low-cost and inclusive health insurance plans in China this year to make up for the lack of coverage for certain populations in China. The report asserts that coverage will gradually expand from first- and second-tier cities to smaller ones, with the prices of products and scope of protection diversifying.

Overall, the BMI scheme has been tweaked to cover more outpatient medical bills, and a special commercial medical insurance scheme covering 49 imported innovative drugs was recently launched in Hainan's Boao Lecheng International Medical Tourism Pilot Zone to lower costs and boost access for patients.

Since Shanghai's commercial supplementary medical insurance coverage Huhuibao launched at the end of April in Shanghai, more than 6.1 million residents have signed up, according to China Pacific Life Insurance, one of nine insurance companies partnered with Shanghai to offer the additional coverage.

A new customized, supplementary medical insurance program available to all people who use Shanghai's current BMI, Huhuibao costs an annual fee of 115 yuan regardless of age, offers medical compensation up to 2.3 million yuan, and covers payments beyond the ambit of the BMI, including for some hospitalization charges and 21 undisclosed but "expensive" medicines for cancer and rare disease, and proton and heavy ion radiation treatments.

Dubai to Expand Medicine Offerings Under Essential Benefits Plan Formulary

Date: June 16, 2021 | Country: UNITED ARAB EMIRATES | Region: MIDDLE EAST | Type: Policy, Pricing & Reimbursement | Keywords: #brandeddrugs #dubaihealthauthority #essentialbenefitsplan #formulary #generic #healthinsurance #isahd #outofpocketpayment #shifa

PRICENTRIC BRIEF:

- On February 18, 2021, the Dubai Health Authority (DHA) rolled out a new, unified formulary (SHIFA), removing several branded medicines that were previously a part of the Essential Benefits Plan—As such, beneficiaries of the AED 600 basic health insurance plan have to either pay out of pocket for medicines not on the formulary or upgrade their coverage plan
- However, the DHA has since reinstated some medicines that were omitted from the formulary, and more are most likely going to be added, potentially some branded medicines
- 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, but the DHA is reportedly updating the list on a weekly basis, and the current count is now 960 products, still mostly generics

THE DETAILS

DUBAI, United Arab Emirates – In mid-February, the Dubai Health Authority (DHA) rolled out a new, unified formulary (SHIFA), removing several branded medicines that were previously a part of the Essential Benefits Plan. As such, beneficiaries of the AED 600 basic health insurance plan have to either pay out of pocket for medicines not on the formulary or upgrade their coverage plan.

However, the DHA has since reinstated some medicines that were omitted from the formulary, and more are most likely going to be added, potentially some branded medicines. 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, but the DHA is reportedly updating the list on a weekly basis, and the current count is now 960 products, still mostly generics.

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.

DHA offered a more limited scope of medicines based on the assumption that Dubaians who want to upgrade their plan can, given its affordability, and due to the pharmaceutical industry's request that the formulary be trimmed.

Having taken effect February 18, 2021, SHIFA replaced the formularies of each hospital and health insurance plan under the DHA's Insurance System for Advancing Healthcare in Dubai (ISAHD), an initiative seeking to provide healthcare for Dubai residents, nationals, and visitors. ISAHD has two main pillars: provide insurance coverage for everyone in Dubai and monitor and introduce enhancements toward a sustainable high-quality healthcare system. Echoing the core aims of ISAHD, the unified formulary is composed of commercially available and licensed outpatient drugs, including innovative drugs, to ensure unified access to the most effective treatments.

HTAs, Approvals, Launches & Price Changes

HTA Decisions: United Kingdom

- NICE in United Kingdom has conducted an assessment of Tecentriq (Atezolizumab; Roche) for Nsclc. Result: Atezolizumab is recommended, within its marketing authorisation, as an option for untreated metastatic non-small-cell lung cancer (NSCLC) in adults if: 1. Their tumours have PD-L1 expression on at least 50% of tumour cells or 10% of tumour-infiltrating immune cells 2. Their tumours do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) mutations and 3. The company provides atezolizumab according to the commercial arrangement.
- NICE in United Kingdom has conducted an assessment of Zeposia (Ozanimod; Celgene) for Multiple Sclerosis. Result: Ozanimod is not recommended, within its marketing authorisation, for treating relapsing remitting multiple sclerosis in adults with clinical or imaging features of active disease. NOT REIMBURSED
- NICE in United Kingdom has conducted an assessment of Opdivo (Nivolumab; Bristol Myers Squibb) for Esophageal Squamous Cell Carcinoma (previously Treated). Result: Nivolumab is recommended, within its marketing authorisation, for treating unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma in adults after fluoropyrimidine and platinum-based therapy. It is recommended only if the company provides nivolumab according to the commercial arrangement. REIMBURSED
- NICE in United Kingdom has conducted an assessment of Ultomiris (Ravulizumab; Alexion Pharma) for Hemolytic Uremic Syndrome. Result: Ravulizumab is recommended, within its marketing authorisation, as an option for treating atypical haemolytic uraemic syndrome (aHUS) in people weighing 10 kg or more: 1. Who have not had a complement inhibitor before or 2. Whose disease has responded to at least 3 months of eculizumab treatment. It is recommended only if the company provides ravulizumab according to the commercial arrangement. REIMBURSED
- NICE in United Kingdom has conducted an assessment of Keytruda (Pembrolizumab; Msd) for Microsatellite Instability-high Cancer (colorectal Cancer). Result: Pembrolizumab is recommended as an option for untreated metastatic colorectal cancer with high microsatellite instability (MSI) or mismatch repair (MMR) deficiency in adults, only if: 1. Pembrolizumab is stopped after 2 years and no documented disease progression, and 2. The company provides pembrolizumab according to the commercial arrangement. REIMBURSED
- NICE in United Kingdom has conducted an assessment of Ultomiris (Ravulizumab; Alexion Pharma) for Hemolytic Uremic Syndrome. Result: Ravulizumab is recommended, within its marketing authorisation, as an option for treating atypical haemolytic uraemic syndrome (aHUS) in people weighing 10 kg or more: 1. Who have not had a complement inhibitor before or 2. Whose disease has responded to at least 3 months of eculizumab treatment. It is recommended only if the company provides ravulizumab according to the commercial arrangement. REIMBURSED
- NICE in United Kingdom has conducted an assessment of Jorveza (Budesonide; Dr Falk Pharma) for Eosinophilic Esophagitis. Result: Budesonide as an orodispersible tablet (ODT) is recommended as an option for inducing remission of eosinophilic oesophagitis in adults. REIMBURSED

HTA Decisions: France

- HAS/TC in France has conducted an assessment of Kesimpta (Ofatumumab; Novartis) for Multiple Sclerosis. Result: The actual benefit of KESIMPTA (ofatumumab) is significant in the indication of the Marketing Authorization SMR (IMPORTANT); ASMR III (MODERATE)
- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Partial Seizures. Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Xarelto (Rivaroxaban; Bayer) for Prevention Of Venous Thromboembolic Events. Result: The actual benefit of XARELTO (rivaroxaban) is significant in the indication of the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Crysvita (Burosumab; Kyowa Kirin) for Hypophosphatemia (x-linked-pediatric). Result: The actual benefit of CRYSVITA (burosumab) is important in the treatment of X-linked hypophosphatemia of severe forms refractory to conventional treatment or of severe complicated forms: - in adolescents with radiographic signs of bone involvement who have completed their bone growth and in adults, - and in pediatric patients and adolescents in the bone growth phase already treated with CRYSVITA (burosumab) for whom continued treatment is necessary. SMR (IMPORTANT); ASMR IV (MINOR)
- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Myoclonic Seizures. Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Xarelto (Rivaroxaban; Bayer) for Prevention Of Venous Thromboembolic Events. Result: The actual benefit of XARELTO (rivaroxaban) is significant in the indication of the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Xarelto (Rivaroxaban; Bayer) for Prevention Of Venous Thromboembolic Events. Result: The actual benefit of XARELTO (rivaroxaban) is significant in the indication of the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Partial Seizures (pediatric). Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Xarelto (Rivaroxaban; Bayer) for Prevention Of Venous Thromboembolic Events. Result: The actual benefit of XARELTO (rivaroxaban) is significant in the indication of the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Crysvita (Burosumab; Kyowa Kirin) for Hypophosphatemia (x-linked). Result: The actual benefit of CRYSVITA (burosumab) is important in the treatment of X-linked hypophosphatemia of severe forms refractory to conventional treatment or of severe complicated forms: - in adolescents with radiographic signs of bone involvement who have completed their bone growth and in adults, - and in pediatric patients and adolescents in the bone growth phase already treated with CRYSVITA (burosumab) for whom continued treatment is necessary. SMR (IMPORTANT); ASMR IV (MINOR)
- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Partial Seizures. Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)

HTA Decisions: France (cont.)

- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Partial Seizures (pediatric). Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Kesimpta (Ofatumumab; Novartis) for Multiple Sclerosis. Result: The actual benefit of KESIMPTA (ofatumumab) is significant in the indication of the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Myoclonic Seizures. Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Retsevmo (Selpercatinib; Eli Lilly) for Thyroid Cancer (medullary-ret Mutant). Result: The actual benefit of RETSEVMO (selpercatinib) is low in medullary thyroid carcinoma. SMR (LOW); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Fycompa (Perampanel; Eisai) for Partial Seizures (pediatric). Result: The actual benefit of FYCOMPA (perampanel) is important in the treatment of partial seizures with or without secondary generalization, in combination with another antiepileptic treatment, in children aged 4 to 11 years and in the treatment of primary generalized tonic-clonic seizures, in combination with other antiepileptic therapy, in children aged 7 to 11 years with generalized idiopathic epilepsy. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Fycompa (Perampanel; Eisai) for Primary Generalized Tonic-clonic Seizures. Result: The actual benefit of FYCOMPA (perampanel) is important in the treatment of partial seizures with or without secondary generalization, in combination with another antiepileptic treatment, in children aged 4 to 11 years and in the treatment of primary generalized tonic-clonic seizures, in combination with other antiepileptic therapy, in children aged 7 to 11 years with generalized idiopathic epilepsy. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Kesimpta (Ofatumumab; Novartis) for Multiple Sclerosis. Result: The actual benefit of KESIMPTA (ofatumumab) is significant in the indication of the Marketing Authorization SMR (IMPORTANT); ASMR III (MODERATE)
- HAS/TC in France has conducted an assessment of Retsevmo (Selpercatinib; Eli Lilly) for Thyroid Cancer (medullary-ret Mutant). Result: The actual benefit of RETSEVMO (selpercatinib) is low in medullary thyroid carcinoma. SMR (LOW); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Primary Generalized Tonic-clonic Seizures. Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Retsevmo (Selpercatinib; Eli Lilly) for Nsclc (ret Fusion+). Result: The actual benefit of RETSEVMO (selpercatinib) is low in non-small cell lung cancer (NSCLC) SMR (LOW); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Primary Generalized Tonic-clonic Seizures. Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)

HTA Decisions: France (cont.)

- HAS/TC in France has conducted an assessment of Dropizal (Opium; Atnahs Pharma) for Diarrhoea. Result: The actual benefit of DROPIZAL 10 mg / mL, oral solution in drops (tincture of Papaver somniferum L., succus siccus (raw opium)) is insufficient to justify coverage by national solidarity in the indication of 'AMM. SMR (INSUFFICIENT)
- HAS/TC in France has conducted an assessment of Keytruda (Pembrolizumab; Msd) for Microsatellite Instability-high Cancer (colorectal Cancer). Result: The actual benefit of KEYTRUDA (pembrolizumab) is insufficient to justify coverage by national solidarity in other situations (patients resectable from the outset). SMR (INSUFFICIENT); COMMENTS WITHOUT ASMR ENCRYPTION
- HAS/TC in France has conducted an assessment of Ecalta (Anidulafungin; Pfizer) for Invasive Candidiasis. Result: The actual benefit of ECALTA (anidulafungin) in the treatment of invasive candidiasis is insufficient in neutropenic patients aged 1 month to 18 years. SMR (INSUFFICIENT)
- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Partial Seizures. Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Myoclonic Seizures. Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Retsevmo (Selpercatinib; Eli Lilly) for Thyroid Cancer (medullary-ret Mutant). Result: The actual benefit of RETSEVMO (selpercatinib) is insufficient in thyroid cancer (except medullary) to justify coverage by national solidarity. SMR (INSUFFICIENT)
- HAS/TC in France has conducted an assessment of Rukobia (Fostemsavir; Viiv Healthcare) for Hiv. Result: The actual benefit of RUKOBIA (fostemsavir) is substantial in the indication of the Marketing Authorization. SMR (IMPORTANT); ASMR III (MODERATE)
- HAS/TC in France has conducted an assessment of Keytruda (Pembrolizumab; Msd) for Microsatellite Instability-high Cancer (colorectal Cancer). Result: The actual benefit of KEYTRUDA (pembrolizumab) is important in the first-line treatment of adult patients with metastatic colorectal cancer with high microsatellite instability (MSI-H) or deficiency of the DNA mismatch repair system (dMMR) not immediately resectable. SMR (IMPORTANT); ASMR IV (MINOR)
- HAS/TC in France has conducted an assessment of Opdivo (Nivolumab; Bristol Myers Squibb) for Metastatic Melanoma (adjuvant Treatment). Result: The actual benefit of OPDIVO (nivolumab) remains substantial in the indication in the Marketing Authorization. SMR (IMPORTANT); ASMR III (MODERATE)
- HAS/TC in France has conducted an assessment of Tukysa (Tucatinib; Seagen) for Breast Cancer (her2+). Result: The actual benefit of TUKYSA (tucatinib) is significant in the indication of the Marketing Authorization. SMR (IMPORTANT); ASMR III (MODERATE)
- HAS/TC in France has conducted an assessment of Ecalta (Anidulafungin; Pfizer) for Invasive Candidiasis. Result: The actual benefit of ECALTA (anidulafungin) in the treatment of invasive candidiasis is substantial in non-neutropenic patients aged 1 month to 18 years. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Partial Seizures. Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)

HTA Decisions: France (cont.)

- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Partial Seizures (pediatric). Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Leptax (Levetiracetam; Hac Pharma) for Partial Seizures. Result: The actual benefit of LEPTAX 750 mg, scored film-coated tablet (levetiracetam) is substantial in the indications in the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Kesimpta (Ofatumumab; Novartis) for Multiple Sclerosis. Result: The actual benefit of KESIMPTA (ofatumumab) is significant in the indication of the Marketing Authorization. SMR (IMPORTANT); ASMR V (ABSENCE)
- HAS/TC in France has conducted an assessment of Kesimpta (Ofatumumab; Novartis) for Multiple Sclerosis. Result: The actual benefit of KESIMPTA (ofatumumab) is significant in the indication of the Marketing Authorization. SMR (IMPORTANT); ASMR III (MODERATE)
- HAS/TC in France has conducted an assessment of Opdivo (Nivolumab; Bristol Myers Squibb) for Nsclc (ipilimumab And Platinum Chemotherapy). Result: The actual benefit of the combination OPDIVO / YERVOY (nivolumab / ipilimumab) is moderate in the indication of the Marketing Authorization. SMR (MODERATE); ASMR IV (MINOR)
- HAS/TC in France has conducted an assessment of Enhertu (Trastuzumab Deruxtecan; Daiichi Sankyo) for Breast Cancer (her2+). Result: The actual benefit of ENHERTU (trastuzumab deruxtecan) is moderate in the indication in the Marketing Authorization. The Commission conditions the maintenance of the moderate AB on the re-evaluation of ENHERTU (trastuzumab deruxtecan) within a maximum period of 18 months from the date of this opinion and on the basis of the results of the phase III study, DESTINY-BREAST 02 (PFS results expected by March 2022 at the latest). SMR (MODERATE); ASMR V (ABSENCE)

HTA Decisions: Germany

- G-BA in Germany has conducted an assessment of Velphoro (Sucroferric Oxyhydroxide; Fresenius) for Hyperphosphatemia. Result: No patient-relevant endpoints were found in the study presented in morbidity or quality of life recorded. Overall, the G-BA comes to the conclusion that an additional benefit of sucroferric oxyhydroxide versus the appropriate comparator therapy is not proven. NO ADDITIONAL BENEFIT OVER COMPARATOR
- G-BA in Germany has conducted an assessment of Lynparza (Olaparib; Astrazeneca) for Ovarian Cancer. Result: There is specific adverse effects predominantly negative effects of olaparib in combination with bevacizumab compared to bevacizumab. Therfore, overall, the G-BA comes to the conclusion that olaparib has no added benefit in combination with bevacizumab versus bevacizumab. Hence, an added benefit not proven. NO ADDITIONAL BENEFIT OVER COMPARATOR
- G-BA in Germany has conducted an assessment of Kanuma (Sebelipase Alfa; Alexion Pharma) for Lysosomal Acid Lipase Deficiency. Result: Clue for a non-quantifiable additional benefit, because the scientific data study does not allow quantification. NON-QUANTIFIABLE ADDITIONAL BENEFIT

HTA Decisions: Germany (cont.)

- G-BA in Germany has conducted an assessment of Yervoy (Ipilimumab; Bristol Myers Squibb) for Nsclc (nivolumab And Platinum Chemotherapy). Result: No added benefit was determined as there are no data for a comparison with the appropriate comparator therapy. Hence an added benefit not proven. NO ADDITIONAL BENEFIT OVER COMPARATOR
- G-BA in Germany has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for Cll (obinutuzumab). Result: No data was submitted by the pharmaceutical company that would be necessary for an assessment of the added benefit over the appropriate comparator therapy. Hence, an added benefit not proven. NO ADDITIONAL BENEFIT OVER COMPARATOR
- G-BA in Germany has conducted an assessment of Kanuma (Sebelipase Alfa; Alexion Pharma) for Lysosomal Acid Lipase Deficiency. Result: Clue for a non-quantifiable additional benefit, because the scientific data study does not allow quantification. NON-QUANTIFIABLE ADDITIONAL BENEFIT
- G-BA in Germany has conducted an assessment of Yervoy (Ipilimumab; Bristol Myers Squibb) for Nsclc (nivolumab And Platinum Chemotherapy). Result: Overall, the results of first-line therapy of patients in metastatic NSCLC without sensitizing EGFR mutation or ALK translocation and PDL1 expression <50% an indication of a minor added benefit for ipilimumab in combination with nivolumab and platinum-based chemotherapy versus platinum-based chemotherapy. MINOR ADDITIONAL BENEFIT
- G-BA in Germany has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for Cll. Result: No data was submitted by the pharmaceutical company that would be necessary for an assessment of the added benefit over the appropriate comparator therapy. Hence, an added benefit not proven. NO ADDITIONAL BENEFIT OVER COMPARATOR
- G-BA in Germany has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for Cll. Result: There was significantly longer progression-free survival rate. Overall, there is therefore an advantage in the morbidity. There is short observation time in the comparison arm therefore there is an advantage in the morbidity. Hence, there is clue for minor added benefit. MINOR ADDITIONAL BENEFIT
- G-BA in Germany has conducted an assessment of Lynparza (Olaparib; Astrazeneca) for Metastatic Castration-resistant Prostate Cancer. Result: Overall survival and other relevant benefits in the patient-reported endpoints to morbidity neither advantages nor disadvantages can be derived from the side effects. Therefore, despite the non-evaluable data on quality of life for olaparib for the treatment of metastatic, castration-resistant prostate cancer with BRCA1 / 2-Mutation a considerable added benefit compared to the appropriate comparator therapy is derived. CONSIDERABLE ADDITIONAL BENEFIT
- G-BA in Germany has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for Cll. Result: No data was submitted by the pharmaceutical company that would be necessary for an assessment of the added benefit over the appropriate comparator therapy. Hence, an added benefit not proven. NO ADDITIONAL BENEFIT OVER COMPARATOR
- G-BA in Germany has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for Cll (obinutuzumab). Result: No data was submitted by the pharmaceutical company that would be necessary for an assessment of the added benefit over the appropriate comparator therapy. Hence, an added benefit not proven. NO ADDITIONAL BENEFIT OVER COMPARATOR
- G-BA in Germany has conducted an assessment of Calquence (Acalabrutinib; Astrazeneca) for Cll (obinutuzumab). Result: There was significantly longer progression-free survival rate. Overall, there is therefore an advantage in the morbidity. There is short observation time in the comparison arm therefore there is an advantage in the morbidity. Hence, there is clue for minor added benefit. MINOR ADDITIONAL BENEFIT

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Drug Approvals: Europe

- ADTRALZA (TRALOKINUMAB) was approved by the EMA for treating adults with moderate to severe atopic dermatitis for whom treatment applied directly to the skin cannot be used or is not sufficient.
COMPANY: LEO PHARMA

- JAYEMPI (AZATHIOPRINE) was approved by the EMA in combination with other immunosuppressive agents for the prophylaxis of transplant rejection in patients receiving allogenic kidney, liver, heart, lung or pancreas transplants.
COMPANY: NOVA LABORATORIES

- ABECMA (IDECABTAGENE VICLEUCEL) was approved by the EMA for the treatment of relapsed and refractory multiple myeloma.
COMPANY: CELGENE

- FINGOLIMOD MYLAN (FINGOLIMOD) was approved by the EMA for the treatment of relapsing-remitting multiple sclerosis with high disease activity.
COMPANY: MYLAN

- EVRENZO (ROXADUSTAT) was approved by the EMA for the treatment of anaemia symptoms in patients with chronic kidney disease.
COMPANY: ASTELLAS

- ABIRATERONE MYLAN (ABIRATERONE ACETATE) was approved by the EMA for the treatment of metastatic prostate cancer.
COMPANY: MYLAN

- MINJUVI (TAFASITAMAB) was approved by the EMA for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem-cell transplant (ASCT).
COMPANY: INCYTE

- BIMZELX (BIMEKIZUMAB) was approved by the EMA for the treatment of moderate to severe plaque psoriasis.
COMPANY: UCB

- BYOOVIZ (RANIBIZUMAB) was approved by the EMA for the treatment of neovascular (wet) age-related macular degeneration, visual impairment due to diabetic macular oedema, proliferative diabetic retinopathy, visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), and visual impairment due to choroidal neovascularisation.
COMPANY: SAMSUNG BIOEPIS

Drug Approvals: United States

- BREXAFEMME (IBREXAFUNGERP) was approved by the FDA for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC).
COMPANY: SCYNEXIS

- WEGOVY (SEMAGLUTIDE) was approved by the FDA as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients.
COMPANY: NOVO

- TEMBEXA (BRINCIDOFOVIR) was approved by the FDA for the treatment of human smallpox disease in adult and pediatric patients, including neonates.
COMPANY: CHIMERIX

- RYPLAZIM (PLASMINOGEN, HUMAN-TVMH) was approved by the FDA for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenia) through its subsidiary, Prometic Biotherapeutics Inc., holder of the biological license application ("BLA") for Ryplazim.
COMPANY: Liminal BioSciences

- ARGATROBAN (ARGATROBAN) was approved by the FDA for prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia (HIT); and as an anticoagulant in adult patients with or at risk for HIT undergoing percutaneous coronary intervention (PCI).
COMPANY: ACCORD HLTHCARE

- ADUHELM (ADUCANUMAB-AVWA) was approved by the FDA as the first and only Alzheimer's disease treatment to address a defining pathology of the disease by reducing amyloid beta plaques in the brain.
COMPANY: BIOGEN

- PREVNAR 20 (PNEUMOCOCCAL 20-VALENT CONJUGATE VACCINE) was approved by the FDA for the prevention of invasive disease and pneumonia caused by the 20 Streptococcus pneumoniae (pneumococcus) serotypes in the vaccine in adults ages 18 years and older.
COMPANY: PFIZER

- EPCLUSA (SOFOSBUVIR & VELPATASVIR) was approved by the FDA for the treatment of adults and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection, without cirrhosis or with compensated cirrhosis; or with decompensated cirrhosis for use in combination with ribavirin.
COMPANY: GILEAD

- MAVYRET (GLECAPREVIR & PIBRENTASVIR) was approved by the FDA for the treatment of adult and pediatric patients 3 years and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A); and for the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.
COMPANY: ABBVIE

- SOAANZ (TORSEMIDE) was approved by the FDA for the treatment of edema associated with heart failure or renal disease.
COMPANY: SARFEZ PHARMACEUTICALS INC

Drug Approvals: United States (cont.)

- REZIPRES (EPHEDRINE HYDROCHLORIDE) was approved by the FDA for the treatment of clinically important hypotension occurring in the setting of anesthesia.
  COMPANY: SINTETICA, SA

- AYVAKIT (AVAPRITINIB) was approved for ADVANCED SYSTEMIC MASTOCYTOSIS by the FDA for adult patients with advanced systemic mastocytosis (AdvSM), including patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).
  COMPANY: BLUEPRINT MEDICINES

- PRADAXA (DABIGATRAN) was approved by the FDA for the treatment of venous thromboembolic events (VTE) in pediatric patients aged 3 months to less than 12 years of age who have been treated with a parenteral anticoagulant for at least 5 days; and to reduce the risk of recurrence of VTE in pediatric patients aged 3 months to less than 12 years of age who have been previously treated.
  COMPANY: BOEHRINGER INGELHEIM

- VERKAZIA (CYCLOSPORINE) was approved by the FDA for the treatment of vernal keratoconjunctivitis (VKC) in children and adults.
  COMPANY: SANTEN

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
TAKEDA	ALUNBRIG	BRIGATINIB	ALUNBRIG TABLETS 1 PACK 28 TABS 157.5 MG	06/01/21	4857.81	4406.87	+450.94	+10.23%
TAKEDA	ALUNBRIG	BRIGATINIB	ALUNBRIG TABLETS 1 PACK 28 TABS 180 MG	06/01/21	4857.81	4406.87	+450.94	+10.23%
TAKEDA	ALUNBRIG	BRIGATINIB	ALUNBRIG TABLETS 1 PACK 28 TABS 30 MG	06/01/21	809.63	734.48	+75.15	+10.23%
TAKEDA	ALUNBRIG	BRIGATINIB	ALUNBRIG TABLETS 1 PACK 28 TABS 90 MG	06/01/21	2428.90	2203.43	+225.47	+10.23%
PIERRE FABRE	BRAFTOVI	ENCORAFENIB	BRAFTOVI CAPSULES 1 PACK 112 CAPS 50 MG	06/01/21	2240.00	2499.54	-259.54	-10.38%
PIERRE FABRE	BRAFTOVI	ENCORAFENIB	BRAFTOVI CAPSULES 1 PACK 168 CAPS 75 MG	06/01/21	5040.00	5623.96	-583.96	-10.38%
PIERRE FABRE	BRAFTOVI	ENCORAFENIB	BRAFTOVI CAPSULES 1 PACK 28 CAPS 50 MG	06/01/21	560.00	624.88	-64.88	-10.38%
PIERRE FABRE	BRAFTOVI	ENCORAFENIB	BRAFTOVI CAPSULES 1 PACK 42 CAPS 75 MG	06/01/21	1260.00	1405.99	-145.99	-10.38%
VERTEX	KALYDECO	IVACAFTOR	KALYDECO GRANULES 1 PACK 56 SACHET 25 MG	06/15/21	10999.76	13398.00	-2398.24	-17.90%
VERTEX	KALYDECO	IVACAFTOR	KALYDECO GRANULES 1 PACK 56 SACHET 50 MG	06/15/21	10999.76	13398.00	-2398.24	-17.90%
VERTEX	KALYDECO	IVACAFTOR	KALYDECO GRANULES 1 PACK 56 SACHET 75 MG	06/15/21	10999.76	13398.00	-2398.24	-17.90%
VERTEX	KALYDECO	IVACAFTOR	KALYDECO TABLETS 1 PACK 28 TABS 150 MG	06/15/21	5499.88	6699.00	-1199.12	-17.90%
VERTEX	KALYDECO	IVACAFTOR	KALYDECO TABLETS 1 PACK 28 TABS 75 MG	06/15/21	5499.88	6699.00	-1199.12	-17.90%
VERTEX	KALYDECO	IVACAFTOR	KALYDECO TABLETS 1 PACK 56 TABS 150 MG	06/15/21	10999.76	13398.00	-2398.24	-17.90%
PIERRE FABRE	MEKTOVI	BINIMETINIB	MEKTOVI TABLETS 1 PACK 168 TABS 15 MG	06/01/21	2450.61	2500.62	-50.01	-2.00%
PIERRE FABRE	MEKTOVI	BINIMETINIB	MEKTOVI TABLETS 1 PACK 84 TABS 15 MG	06/01/21	1225.30	1250.31	-25.01	-2.00%
BAYER	NUBEQA	DAROLUTAMIDE	NUBEQA TABLETS 1 PACK 112 TABS 300 MG	06/01/21	3086.56	3890.00	-803.44	-20.65%
ABBVIE	VENCLYXTO	VENETOCLAX	VENCLYXTO TABLETS 1 PACK 112 TABS 100 MG	06/01/21	4788.00	5006.40	-218.40	-4.36%
ABBVIE	VENCLYXTO	VENETOCLAX	VENCLYXTO TABLETS 1 PACK 14 TABS 10 MG	06/01/21	59.85	62.58	-2.73	-4.36%
ABBVIE	VENCLYXTO	VENETOCLAX	VENCLYXTO TABLETS 1 PACK 14 TABS 100 MG	06/01/21	598.50	625.80	-27.30	-4.36%
ABBVIE	VENCLYXTO	VENETOCLAX	VENCLYXTO TABLETS 1 PACK 7 TABS 100 MG	06/01/21	299.25	312.90	-13.65	-4.36%
ABBVIE	VENCLYXTO	VENETOCLAX	VENCLYXTO TABLETS 1 PACK 7 TABS 50 MG	06/01/21	149.63	156.45	-6.82	-4.36%
ABBVIE	VENCLYXTO	VENETOCLAX	VENCLYXTO TABLETS 1 PACK 112 TABS 100 MG	06/01/21	4788.00	5006.40	-218.40	-4.36%
ABBVIE	VENCLYXTO	VENETOCLAX	VENCLYXTO TABLETS 1 PACK 14 TABS 10 MG	06/01/21	59.85	62.58	-2.73	-4.36%
ABBVIE	VENCLYXTO	VENETOCLAX	VENCLYXTO TABLETS 1 PACK 14 TABS 100 MG	06/01/21	598.50	625.80	-27.30	-4.36%
ABBVIE	VENCLYXTO	VENETOCLAX	VENCLYXTO TABLETS 1 PACK 7 TABS 100 MG	06/01/21	299.25	312.90	-13.65	-4.36%
ABBVIE	VENCLYXTO	VENETOCLAX	VENCLYXTO TABLETS 1 PACK 7 TABS 50 MG	06/01/21	149.63	156.45	-6.82	-4.36%

Drug Launches: Europe & U.S.

Country	Generic Name	Product Group	Company	Indication	Therapeutic Areas	Product Approval Date	Start Date (Launch date)
GERMANY	TAGRAXOFUSP	ELZONRIS	STEMLINE THERAPEUTICS	BLASTIC PLASMACYTOID DENDRITIC CELL NEOPLASM	ONCOLOGY	7/1/2021	01/06/2021
GERMANY	DOSTARLIMAB	JEMPERLI	GLAXOSMITHKLINE	ENDOMETRIAL CANCER (dMMR)	ONCOLOGY	21/04/2021	01/06/2021
GERMANY	CENOBAMATE	ONTOZRY	ARVELLE THERAPEUTICS	PARTIAL-ONSET SEIZURES	NEUROLOGY	26/03/2021	01/06/2021
GERMANY	BEROTRALSTAT	ORLADEYO	BIOCRYST PHARMACEUTICALS	HEREDITARY ANGIOEDEMA	NA	30/04/2021	01/06/2021
GERMANY	PONESIMOD	PONVORY	JANSSEN	MULTIPLE SCLEROSIS (RELAPSED)	NA	19/05/2021	01/06/2021
ITALY	AVAPRITINIB	AYVAKYT	BLUEPRINT	GASTROINTESTINAL STROMAL TUMOR	ONCOLOGY	24/09/2020	14/06/2021
UNITED KINGDOM	BELANTAMAB MAFODOTIN	BLENREP	GLAXOSMITHKLINE	MULTIPLE MYELOMA	ONCOLOGY	25/08/2020	02/06/2021
UNITED STATES	ADUCANUMAB	ADUHELM	BIOGEN	ALZHEIMER'S DISEASE	NA	07/06/2021	15/06/2021

Price Changes: Europe & U.S.

Country	Generic Name	Product Group	Company	Therapeutic Area	Avg. Price Change all SKU	First Pricing date
FRANCE	LAMIVUDINE	EPIVIR	VIIV HEALTHCARE	HEPATITIS B	-10.00%	01/01/2002
FRANCE	DARUNAVIR	PREZISTA	JANSSEN	HIV	-12.50%	13/08/2009
FRANCE	GEFITINIB	IRESSA	ASTRAZENECA	ONCOLOGY	-20.00%	22/01/2010
FRANCE	OCTREOTIDE	SANDOSTATIN LAR	NOVARTIS	ONCOLOGY	-20.00%	19/10/2005
FRANCE	ANAGRELIDE	XAGRID	SHIRE	ONCOLOGY	-12.50%	24/01/2006
SPAIN	BILASTINE	BILAXTEN	MELYFARMA	RESPIRATORY	-45.37%	6/1/2017
UNITED STATES	SARGRAMOSTIM	LEUKINE	PARTNER TX	HEMATOLOGY	+5.00%	10/07/2015
ITALY	BEZAFIBRATE	BEZALIP	AUROBINDO PHARMA	CVS	-0.19%	01/01/2016

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UNITED STATES

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