Windrose Consulting Group Global News Roundup: Q3 2022

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- This edition of the Windrose Consulting Group Global News Roundup: Q3 2022, covers Life science industry highlights from:
  - US
  - Australia, Canada and the UK
  - France
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  - UK
  - Saudi Arabia
  - South Africa
  - China
  - Brazil

Medicare Legislation Passes US Senate

DETAILS

- On August 16th, 2022, President Biden signed the Inflation Reduction Act into law which would bring reforms to Medicare spending and coverage, impacting manufacturers' long-term P&MA strategy and payer decision-making
- The law includes several provisions related to prescription drug spending by the federal government as well as changes to capping patient out-of-pocket costs that will take place in the upcoming years
- At a high level, the bill would:
    1. Allow the federal government to negotiate prices on the highest Medicare expenditure single-source drugs
    2. Limit insulin to $35 per month for people with Medicare, and cap out-of-pocket spending on all drugs at $2,000 a year
    3. Reduce patient's cost share to $0 for Advisory Committee on Immunization Practices-recommended vaccines covered under Medicare Part D
    4. Require manufacturers to pay rebates to Medicare if their increase in drug prices outpace the inflation rate

INDUSTRY IMPLICATIONS

1. Price negotiations for high-cost drugs in Medicare:
    - Manufacturers may now face negotiations with Medicare, likely resulting in price and revenue reductions
    - Navigating negotiation strategies and establishing which evidence and associated value stories are most effective will become imperative for manufacturers by 2026
    - Although presently the drugs selected are drugs that have been on the market for 10 years, the legislation sets a precedent for direct negotiation and this 10-year restriction could evolve if high-budget impact Medicare drugs come to market

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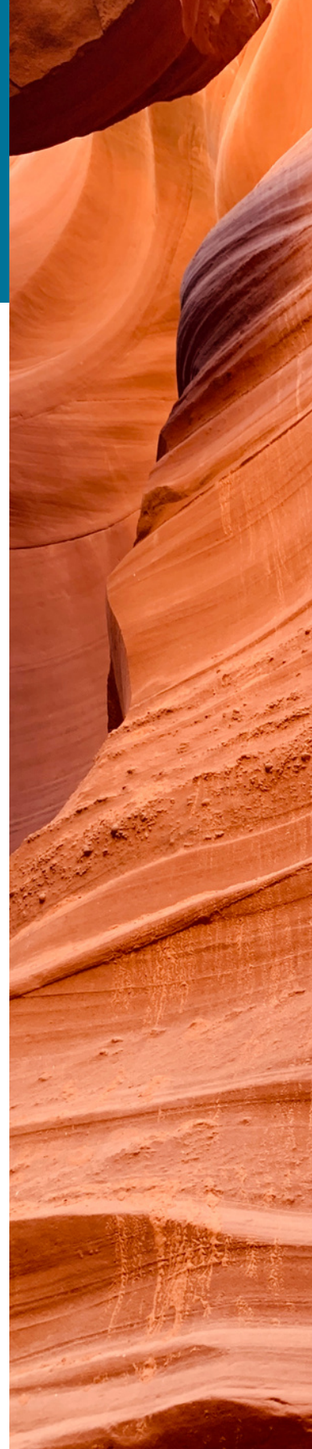


Medicare Legislation Passes US Senate

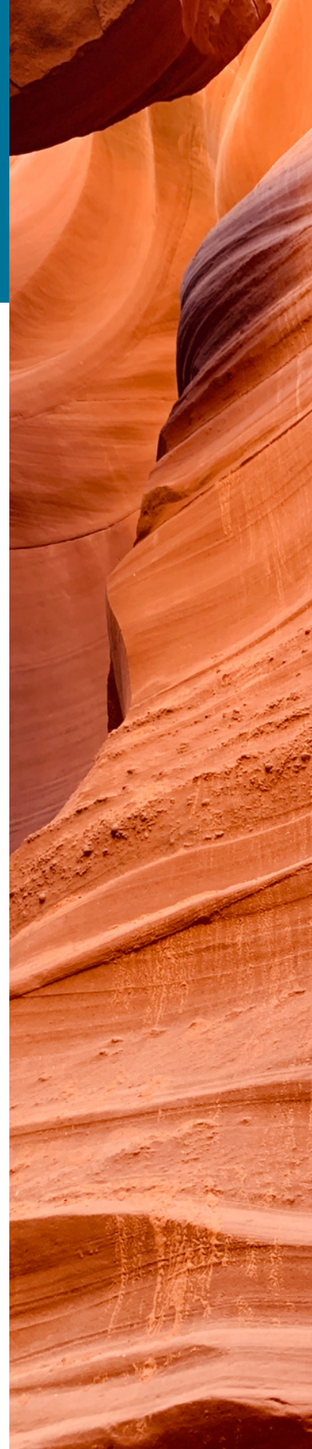
INDUSTRY IMPLICATIONS (CONTINUED)

2. Part D $2,000 out-of-pocket cap:
   - Reduction in patient price sensitivity could benefit manufacturers by translating to higher patient fulfillment or even increased uptake for branded products
   - For high-cost products where the $2,000 cap is reached quickly, the impact of different tier status between the high-cost products would also be reduced
   - The $2,000 cap simplifies the complex prior out-of-pocket structure (co-pay/co-insurance based on drug tier, coverage gap, catastrophic coverage) for Part D drugs
3. Elimination of cost-sharing for Part D vaccines:
   - With beneficiary cost-sharing eliminated, there is uncertainty around how existing management tools (i.e., tier status, prior authorizations) will be leveraged to manage vaccine utilization, or if any new utilization management tools will be created
4. Rebate for price hikes greater than the rate of inflation:
   - The inflation-based rebate policy will directly limit the increase in cost for Medicare and its beneficiaries' out-of-pocket cost-sharing, potentially leading to increased launch prices or price increases in the private market

ADDITIONAL RESOURCES

SENATE DEMOCRATS

SENATE DEMOCRATS



New AUS-CAN-UK cross-border HTA alliance has been revealed

DETAILS

- In September 2022, a new cross-border HTA alliance between Australia, Canada and the UK has been revealed
- The AUS-CAN-UK Collaboration Arrangement brings together six “like-minded” organizations: NICE, Healthcare Improvement Scotland, Health Technology Wales, the All Wales Therapeutics & Toxicology Centre, CADTH and the Australian Government Department of Health and Aged Care
- This agreement will allow the partners to work together on shared priorities to identify solutions to some of the common challenges they face
- Five initial priority areas have been agreed:
    1. Covid-19-related intelligence sharing, which also includes management of Covid-19 medicines with good evidence but no plans for marketing approval
    2. Future-proofing of HTA systems: processes to better anticipate challenges in HTA evaluations (i.e., real-world evidence)
    3. Collaborating with regulators: improving co-operation between regulatory & HTA agencies in the 3 countries
    4. Work-sharing & efficiency gains: exploring feasibility of using HTA assessments, including a pilot for a Joint Clinical Assessment (JCA)
    5. Digital and artificial intelligence: sharing information on developments of these technologies

INDUSTRY IMPLICATIONS

- While the AUS-CAN-UK Collaboration Arrangement is a formal partnership that encompasses more than one geographic region, it includes similar market archetypes with a focus on cost-effectiveness
- The extent it will impact evaluation of individual products is to be determined, but with fewer knowledge barriers, manufacturers will have to prioritize transparency, particularly in their health economic evaluations
- Although at early stages of development, the pilot JCA may have implications for manufacturer evidence requirements in these markets; it will be interesting to understand what differences, if any, evolve between the European Pan-EU JCA system that has faced considerable resistance

ADDITIONAL RESOURCES

NICE.ORG

Highly-rated ASMR drugs in France to be subject to updated economic evaluations to limit health expenditure impact

DETAILS

- Starting in 2023, the Haute Autorité de Santé (HAS) will be implementing new rules for drugs with ASMRs I-III regarding their health economic evaluation
- France will now gauge a product's potential for significant health insurance expenditure impact by accounting for a drug's forecast pre-tax sales, rather than tax-inclusive sales, for both the second year of marketing for its registered indication and in the 12 months prior to any renewal application
- Manufacturers must submit to HAS and CEPS (Economic Committee):
  - Claims on the impact on the organization of care, or the conditions of patient care
  - An estimate of forecast sales over 3 years in the registered indication, or the indication of interest
  - An estimate of projected population over 3 years in the registered indication or indication of concern
- Health economic evaluations will be required if:
  - The product is an advanced therapy medicinal product, based on its impact on organization of care
  - If the sales are, or exceed €20M / year, excluding tax
  - If the company claims an impact on the organization of care, professional practice, or the conditions of patient care
- Companies will be exempt from evaluations if:
  - The product is not protected by any patent or supplementary protection certificate
  - When the application is expanding to a pediatric indication from an already launched adult indication
  - If the treated population increases by <5% over 2 years

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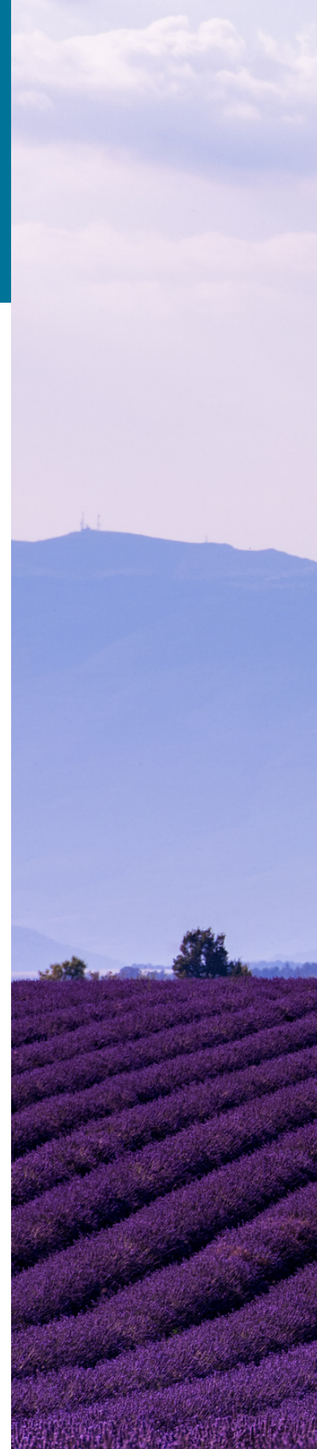


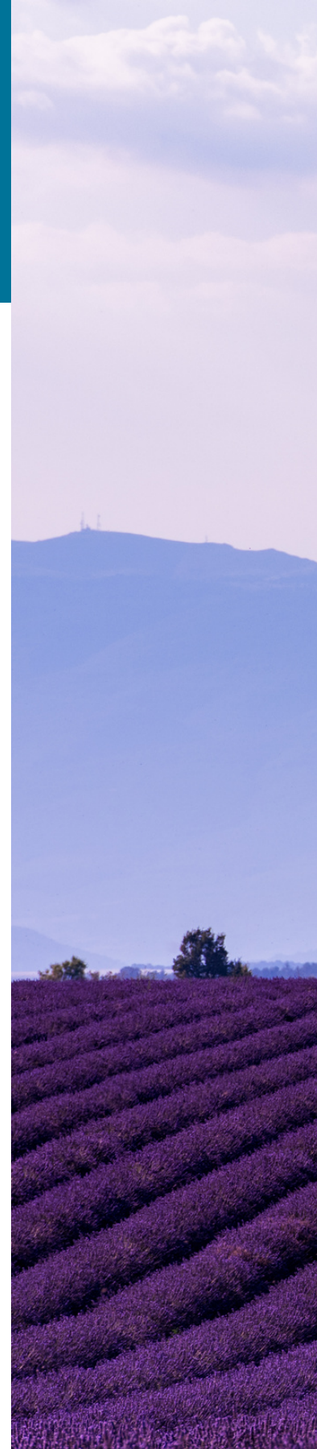
Highly-rated ASMR drugs in France to be subject to updated economic evaluations to limit health expenditure impact

INDUSTRY IMPLICATIONS

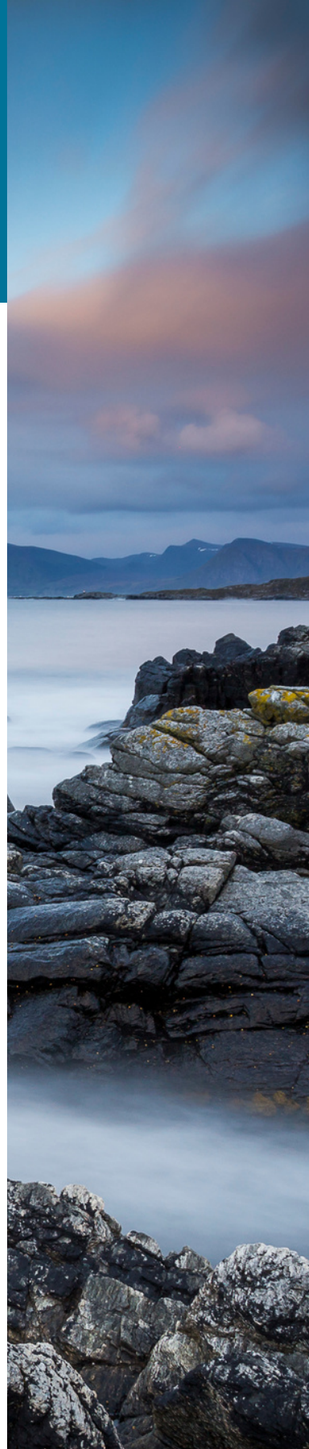
- The new adjustments have consequences for new launches, as well as older products with significant budget impact and may be required to undergo a health economic assessment
- Specifically including breakthrough drugs in rare indications, drugs with broad populations, and existing drugs that may already address broad populations
- The impact of the adjusted strategy on current products may prompt manufacturers to revaluate long-term pricing strategies or build in prospective indication expansions to boost a product's sales and reduce any potential loss of revenue from an aggressive economic review
- Specifically, manufacturers may be further motivated to investigate pediatric extensions to avoid health economic evaluations for their ATMPs that have high health expenditure impact
- Manufacturers should be advised to evaluate the trade-off of adjusting the pricing strategy to fall below the €20M / year pre-tax sales threshold to avoid a healthcare economic evaluation

ADDITIONAL RESOURCES

LA HAUTE AUTORITÉ DE SANTÉ (HAS)



An agreement between 5 Nordic countries on a common strategy for closer collaboration on access to hospital drugs inches closer



DETAILS

- The Nordic Pharmaceuticals Forum (Nordisk Lægemiddel Forum, NLF) composed of Finland, Iceland, Norway, Sweden and Denmark was established in 2015
- The collaboration focuses on sharing knowledge and working towards common Nordic solutions
- To varying degrees, Denmark, Finland, Norway and Sweden constitute limited markets for pharmaceutical manufactures and from the NLF perspective, they are struggling to secure supplies of hospital pharmaceuticals
- But recent regulatory and political discussion among the Nordic states has seen the prospect of enhanced cooperation and eventually joint procurement as a way to gain greater leverage in pricing and reimbursement negotiations

INDUSTRY IMPLICATIONS

- For manufacturers, this brings opportunities to access a broader population through value-based agreements at the NLF level
- However, joint procurement on the Nordic-level scale resulting in combined volumes, will likely lead to far tougher evidence scrutiny and negotiations on price with manufacturers than with individual countries alone

ADDITIONAL RESOURCES

AMGROS

NICE publishes the Real-Word Evidence framework

DETAILS

- In June 2022, the National Institute for Health and Care Excellence (NICE) published a new framework to advance the use of Real-World Evidence (RWE) by identifying when to use RWE and the best practices for planning, conducting, and reporting RWE
- The 2021 to 2026 Strategy is to be used to resolve gaps in knowledge and drive access to innovations for patients
- The new methodologies seek to improve data inputs for NICE's decision making

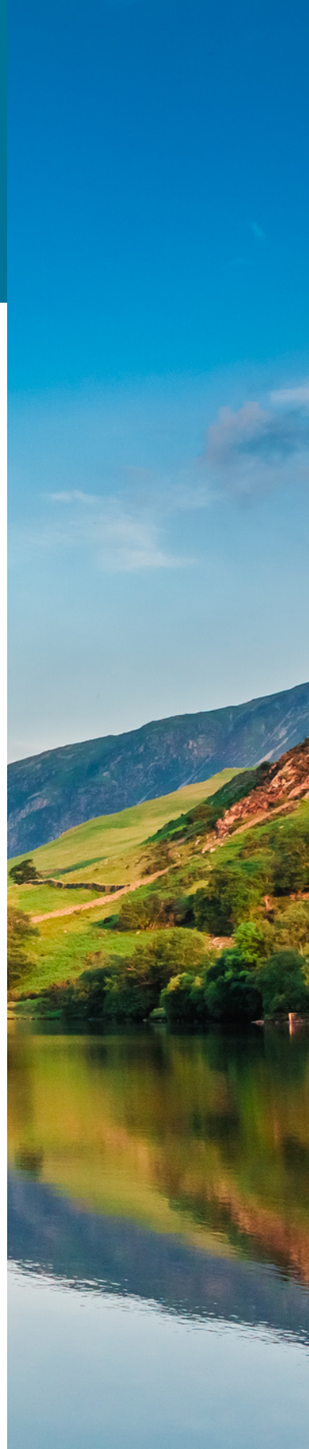
INDUSTRY IMPLICATIONS

- The RWE framework has various ramifications, the most notable of which is the compilation of rigorous evidence to demonstrate the value of a new asset
- The level of evidence may increase in rigor and robustness when compared to earlier evidence gathered within the same therapeutic area, thus limiting the translation of the new product's net health benefit and total potential value to the healthcare system
- Because of the limited patient population size, products for orphan and rare diseases may struggle to provide solid evidence
- Nonetheless, if RWE is established in alignment with the framework, this could help identify the total potential value of the new product which in turn leads to a higher actual value, increases the perception of stakeholders, and potentially faces less limitation of willingness-to-pay

ADDITIONAL RESOURCES

NICE.ORG

NICE.ORG



The Kingdom of Saudi Arabia has initiated the development of its own clinical guidelines encompassing all indications

DETAILS

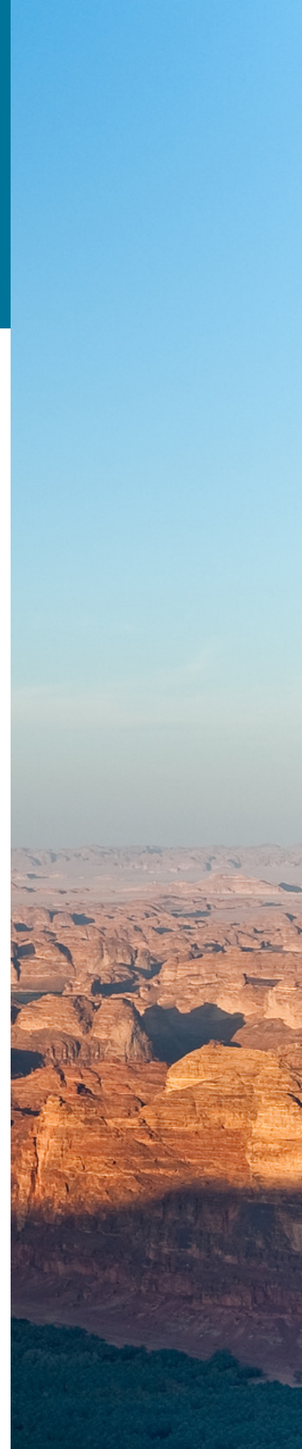
- The Deputyship of Therapeutic Affairs at the Ministry of Health outlined the aims, missions, and values of the guidelines in the first issue of the Saudi Journal of Clinical Pharmacy (SJCP)
- Going forward, the guidelines are intended to contribute to and enhance the dynamic field of clinical pharmacy in the context of the Kingdom of Saudi Arabia's (KSA) evolving healthcare environment

INDUSTRY IMPLICATIONS

- Saudi Arabia currently uses either international reference pricing (IRP) or therapeutic reference pricing to establish the price of medicines
- However, clinical guidelines may impact on what is considered the most appropriate internal reference groups by outlining standard-of-care, and therefore the Saudi Food and Drug Authority (SFDA) could use the guidelines to influence price decisions
- As such manufacturers may need to be prepared to work more closely with the KSA clinical community in advance to launch, in order to create Key Opinion Leader (KOL) advocacy for the inclusion of products in local guidelines

ADDITIONAL RESOURCES

- Data on file (no link – info provided by network partner)



South Africa’s new National Health Insurance scheme is set to be introduced in several stages

DETAILS

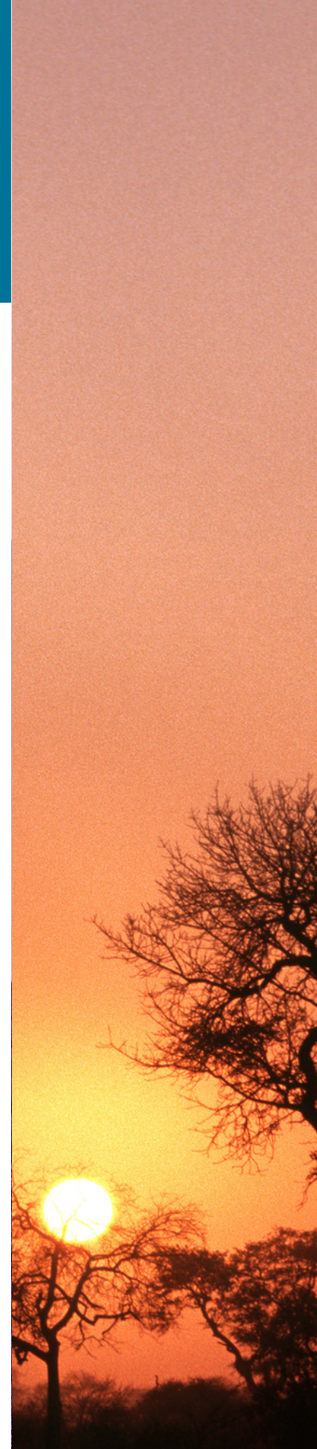
- In South Africa, the public sector provides healthcare to ~80% of the population, while the private sector provides healthcare to the remaining ~20%
- In June 2018, the government introduced the National Health Insurance (NHI) Bill to the public to address inequality in South Africa's health sector and in July 2022, the parliament released further information on how it will be introduced
- Ultimately, private medical aids and hospitals are set to be scrapped, meaning state infrastructure will have to rapidly expand, and scale services to cope with treating all South Africans
- The NHI envisages a ‘universal’ system for everyone in the country where the NHI Fund purchases services from both public and private providers

INDUSTRY IMPLICATIONS

- For manufacturers, the proposed NHI has the potential to greatly improve access to pharmaceuticals for those currently reliant on South Africa’s sub-par public sector or those who choose to pay out-of-pocket for access to the private sector
- However, the potential large bargaining power of an NHI body will exert downward pressure on price negotiations with manufacturers

ADDITIONAL RESOURCES

BUSINESS TECH



Hope City has imported more than 200 first-in-class licensed drugs and devices

DETAILS

- The Hainan Boao Lecheng International Medical Tourism Pilot Zone, also known as Hope City, has been a target destination for many innovative therapies seeking early access in China recently
- Hope City has been granted autonomy from the State Council and as such has the unique opportunity to treat patients with drugs, devices, and innovative therapies approved overseas, but not yet approved in China
- It is reported that by the beginning of 2022, Hope City has imported more than 200 first-in-class licensed drugs and devices including 39 oncology drugs, 38 rehabilitation devices, 31 ophthalmic devices, and 28 cardiac devices

INDUSTRY IMPLICATIONS

- Access options like these help manufacturers of innovative therapies get to Chinese patients early, well ahead of National Medical Products Administration (NMPA) approval
- This window of early access is valuable in building goodwill and Key Opinion Leader (KOL) support, as well as Chinese data and real-world evidence, which are key for eventual regulatory approval
- Manufacturers should also consider that the benefits of increased KOL support and experience in the CN population may also indirectly improve chances of being considered for National Reimbursement Drug List (NRDL) listing in CN

ADDITIONAL RESOURCES

LECITYHN.COM

Brazil could soon have an explicit cost-effectiveness threshold for new medicines

DETAILS

- The National Commission for the Incorporation of Technologies (CONITEC) in the Brazilian Public Health System (SUS) has recently published a report with “recommendations” to establish a cost-effectiveness threshold for the inclusion of new drugs, tests, and procedures in public health
- The threshold is to create a sustainable system that not only invests in curative care but also in prevention and rehabilitation and monitoring of the life cycles of the various types of care
- The proposal is in line with other methodologies already studied by CONITEC, such as the efficiency frontier and the use of multi-criteria in decision-making, in order to ensure that new technologies, in fact, bring value to the health system
- Brazil has chosen the Gross Domestic Product per inhabitant (GDP per capita), currently in the range of R$40,000, as the maximum reference per year
    - However, it is proposed that there should flexibility for rare, severe, pediatric, and endemic diseases which may warrant up to three times the ceiling – that is, ~R$120,000 for each year of life in good health

INDUSTRY IMPLICATIONS

- With greater importance to the cost-effectiveness threshold, this risks gaining greater influence in public sector evaluations which would restrict access mainly to more expensive procedures
- However, CONITEC has stressed to manufacturers that it believes cost-effectiveness should be considered within a range of factors in decision making
- Therefore, as a highly cost-sensitive market, it is likely that cost minimization will remain the key driver in evaluations with comparative data, and real-world evidence becoming increasingly important in achieving public coverage

ADDITIONAL RESOURCES

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