Windrose Consulting Group Global News Roundup: Q1 2022

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- This edition of the Windrose Consulting Group Global News Roundup: Q1 2022, covers Life science industry highlights from:
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Public consultation has been underway in Brazil on a reform of the country's 17-year-old drug pricing framework; the consultation is now closed and the pharma sector is waiting on further updates from CMED

DETAILS

- The government proposes to update the pricing regulations originally set out in CMED's (Drug Market Regulation Chamber) Resolution of March 2004, which defined the mechanism for setting maximum ex-factory launch prices of drugs based on a six category classification system*
- CMED proposes the creation of three additional pricing groups: category VII for biosimilar drugs, category VIII consisting of several subcategories relating to new presentations of already marketed active ingredients, and category IX for medicines subject to a transfer of ownership
- These new subgroups are being proposed to address a notable increase in the number of pricing requests that cannot be accommodated within the current methodology

INDUSTRY IMPLICATIONS

- The pricing rules for innovative drugs – namely categories I and II of CMED's existing classification system – will remain the same apart from minor wording changes aimed at clarifying the difference between these categories
- The updated definition of category I specifies that the comparator against which the new drug will be assessed to determine added value must be a drug currently used for the same indication in Brazil
- The new wording provides some clarity to sponsors in terms of clinical data requirements, but is not aimed at making the hard-to-reach category I status any more accessible, notably without relevant head-to-head data

ADDITIONAL RESOURCES

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CNS

*Regarding the existence or not of a comparator, NMEs drugs are classified by CMED, in Category I or II. The medicine included in Category I is considered innovative. The drug classified in Category II is not considered to have demonstrated scientifically proven superiority over the standard treatment or has no patent on the product in the country. Non-NMEs are scored as Category III – VI. Categories III – V represent new presentations and/or dosing forms of existing drugs or combinations. Category VI represents generics.

In Brazil, the Ministry of Health announces a campaign “Somos Todos Raros” (“We Are All Rare”) to train professionals to recognise rare diseases

DETAILS

- The Ministry of Health will train healthcare professionals who work in the Unified Health System (SUS) to recognize patients with rare pathologies thus enabling more timely referrals to specialized services
- Rare diseases are characterized by often unknown signs and symptoms which tend to vary between individuals with the same disease; patients with rare diseases in Brazil typically consult up to 10 doctors from different specialties before a diagnosis is reached
- In addition, the Brazilian Rare Disease Network (BRDN) is under development, comprising 40 institutions, including 18 university hospitals, 17 Rare Diseases Reference Services and five Newborn Screening Reference Services

INDUSTRY IMPLICATIONS

- Delayed diagnoses and limited access to resources present major barriers to the utilization of orphan medical products in the real-world setting in Brazil
- From an industry perspective, clinical research on rare diseases faces many challenges when conducting trials in small populations; affected patients can be hard to identify, generally geographically dispersed, and often children
- Initiatives such as this not only improve patient access to more timely care, but also help industry identify patient populations for future clinical research – they also present opportunities for industry collaboration in terms of educational support

ADDITIONAL RESOURCES

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SOMOS TODOS RAROS

Domestic PD-1/PD-L1 competition in China is fierce; further rounds of medical insurance negotiations could see the annual cost of PD-1/PD-L1 products continue to fall

DETAILS

- As of end of December 2021, the National Medical Products Administration (NMPA) had approved a total of 12 PD-1/PD-L1 products, involving 11 cancer types and 44 indications, of which eight are domestically produced and four are imported
- PD-1/PD-L1 products participating in medical insurance in 2022 are all domestic products, namely PD-1 products
- In addition to the approved indications, both domestic and foreign pharmaceutical companies are also competing for new indications for their products, and everyone has entered a race against time in research and development
- At present, there are more than 100 companies known to still be developing PD-1 products in China

INDUSTRY IMPLICATIONS

- At present, the resistance to listing foreign PD-1/ PD-L1s in the medical insurance catalogue has been mainly due to their relatively high price – a price bar that continues to be eroded by domestic entrants
- The fierce competition among both domestic and foreign pharmaceutical companies will inevitably affect latecomers who have not yet commercialized their products
- Companies will unavoidably fight price wars in the face of limited market space – notably in medical insurance negotiations where domestic companies are more willing and able to give away deeper discounts than their Western counterparts

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The Center for Drug Evaluation (CDE) of the State Drug Administration in China announced the draft of the “Guidelines for Clinical Research and Development of Antitumor Drugs Oriented to Clinical Value,” cooling the "me-too" market

DETAILS

- At the end of 2021, the Center for Drug Evaluation (CDE) anti-tumor drug new policy was released to combat pseudo-innovation termed “me-worse” drugs
- The "Guiding Principles" propose that new drug development should provide patients with better (more effective, safer or more convenient) treatment options as a higher goal, and clearly points out that "control drugs" are the basis for reflecting the clinical value of new drugs
- The “Guiding Principles” make it clear that when a non-optimal treatment is selected as a control, even if the clinical trial achieves the pre-set research objectives, it does not mean that the experimental drug can meet the actual needs of patients in clinical practice
- Therefore, the CDE emphasizes that when choosing an active drug as a control, attention should be paid to whether the active control reflects and represents the best treatment option for the target patients in clinical practice
- If there is no standard treatment in clinical practice, best support care (BSC) can be selected; BSC should be preferred as a control rather than a placebo

INDUSTRY IMPLICATIONS

- The “Guiding Principles” infer that when pharmaceutical companies developing “me-too” products apply for clinical trials of anti-tumor drugs in the future, they will need to conduct a "head-to-head" comparison, otherwise there will be no way to market them
- Many industry insiders agree that this policy will directly hit the large number of domestic pseudo-innovative "me-too" drugs and will usher in a major purge

ADDITIONAL RESOURCES

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SINA FINANCE

Note: In China, it takes a long time for announcements such as this to enter into practice and become relevant.

Pan-European HTA regulation launched January 2022

DETAILS

- Pan-European health technology assessment (HTA) regulation came into effect in January 2022; however, use will not become mandatory until 2025 so member states have time to adapt their national legislation
- The objective of the regulation is to avoid multiple country-specific assessments and to improve the functioning and transparency of HTA
- The regulation includes a joint clinical assessment (JCA), joint scientific consultation (JSC), and horizon scanning, focusing on the relative clinical effectiveness and safety of a new health technology in the context of the current treatment paradigm
- However, EU member states will retain responsibility for determining the additional clinical benefit, and making pricing and reimbursement decisions
- Complementary clinical analyses and assessment of non-clinical domains (i.e., pharmacoeconomic evaluations) will also be carried out on a market-level basis to support national decision-making

INDUSTRY IMPLICATIONS

- The outcomes of the JCA will likely inform clinical value and pricing assessments for all EU member states; member states will be required to attach JCAs to their national assessment reports and to explain how they used the JCAs in their national processes
- 2 major EU members, France and Germany, are to play key roles in shaping the methods and procedures; the G-BA (Federal Joint Committee) IQWiG (Institute for Quality and Efficiency in Health Care) and the HAS (Public Health Department) are represented on more EUnetHTA working groups than any other national agencies
- The extent that country-specific regulations and principles will be retained remains to be determined; in DE, this could speed up the early benefit assessment from the current six months to 10 weeks
- As such, for products launching after 2027, developing clinical programs in-line with JCA requirements and early engagement with the JSC will be crucial to ensure alignment

ADDITIONAL RESOURCES

WHITEPAPER

DELIVERABLES

JSC

EFPIA filed proposal for P&R throughout the EU and proposal for equity-based tiered pricing

DETAILS

- EFPIA (European Federation of Pharmaceutical Industries & Associations) has worked on a series of proposals effective April 2022 to improve patient access to innovative medicines and reduce inequalities across Europe including:
    1. A commitment from the industry to file pricing and reimbursement applications in all EU countries no later than 2 years after EU market authorization
    2. The creation of a European Access Portal where marketing authorization holders (MAH) can provide timely information regarding the timing and processing of pricing and reimbursement (P&R) applications in the EU-27 countries
    3. A conceptual framework for Equity-Based Tiered Pricing (EBTP)
    4. Novel payment and pricing models

INDUSTRY IMPLICATIONS

- Modelling predicts that this commitment would boost the availability of medicines from 18% to 64% in several countries and reduce time to access by 4-5 months
- Aggregate or therapeutic level analyses will be published on the portal every six months; participation in the initiative will be voluntary, but the EFPIA expects a strong industry response to provide further transparency on challenges faced in launching across EU markets
- EBTP is to ensure that ability to pay across countries is considered in the prices of innovative medicines, to reduce unavailability of new medicines and access delays
- Mandatory price discounts between EU markets may require manufacturers to change international reference pricing tactics within the EU entirely

ADDITIONAL RESOURCES

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ADDRESSING INEQUALITIES

ROOT CAUSE DELAYS

AIFA budget impact evaluation now includes indirect costs

DETAILS

- In March 2021, AIFA (the Italian Medicines Agency: Agenzia Italiana del Farmaco) implemented new guidelines, which stated for the first time that indirect costs, such as productivity loss, would be considered in budget impact models and economic evaluations
- 1-year later, in March 2022, Italian payers have confirmed that the guidelines are being implemented and indirect cost impact will be considered when it is relevant to the burden of disease

INDUSTRY IMPLICATIONS

- In Italy, budget impact has historically been a key driver of payer decision making and the inclusion of indirect costs can be extremely beneficial, especially for diseases that have a low direct-cost burden in terms of healthcare resource utilization (e.g., hospitalizations and emergency visits)
- To support dossier submissions, the burden of disease should be well established prior to introducing the budget impact model, with emphasis on areas that will be translated into indirect costs

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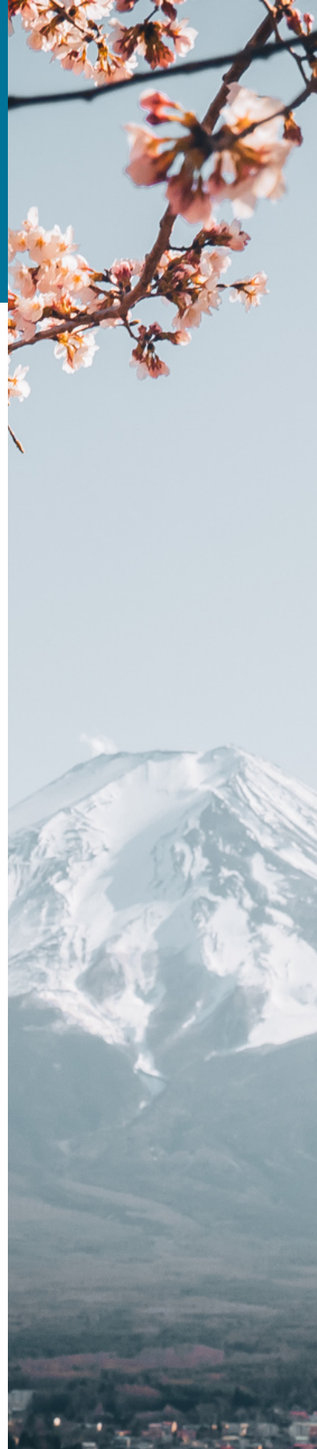
MARKET ACCESS ITALY

In fiscal 2022, the Japanese Chuikyo decided to keep “using cost-effectiveness evaluation for price adjustment,” rather than adapting its use for determining possibility of reimbursement



DETAILS

- The cost-effectiveness assessment (CEA) in Japan is a new system that was fully introduced in April 2019 to evaluate medical technology
- When it comes to reimbursement considerations, “usefulness / safety” remains set as the main evaluation index
- However, in applying the CEA, "economy" is taken into consideration, with the main aim being to set appropriate reimbursement prices for pharmaceuticals and medical materials
- In fiscal 2022, the Chuikyo (Central Social Insurance Medical Council) decided that it was too early for major changes to the system and that it would retain these guidelines, instead focusing on the correction in operational defects of the system to date

INDUSTRY IMPLICATIONS

- While the CEA mechanism is complex, it can be roughly summarized as follows:
  - For new drugs and medical devices that meet requirements (e.g., "high price" and "significant impact on medical insurance finances”) whether "it is more Cost Effective than similar drugs and medical technologies, or inferior” is judged based on the data alone
  - If it is judged as Cost Effective, the price (drug price, material price) will be left unchanged
  - If it is judged that Cost Effectiveness is inferior, the price will be reduced
  - If extremely Cost Effective "the cost is low, but the effect is excellent or the same,” the price can be raised

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GEM MED

Mexico cuts the order of medicines through UNOPS for 2022 after shortage problems

DETAILS

- In 2020, the AMLO (Andrés Manuel López Obrador) administration executed an agreement with United Nations Office for Project Services (UNOPS) for the procurement of drugs for 2021-2024 on behalf of federal entities and 26 of Mexico's 32 states
- The Institute of Health for the Welfare of the United Mexican States (INSABI) was nominated to be the responsible body for recording the aggregate demand
- Medicine shortages were a key driver for the agreement and one of the main criticisms of the current government after worsening in 2019 due to budget cuts and changes in procurement imposed by López Obrador, who assumed the Presidency on December 1, 2018
- However, a year and a half after the signing, the ambition of the agreement has been significantly reduced as both parties recognize "deficiencies" in a process fraught with delays
- The order for the second half of 2022 will be considerably less than for 2021: UNOPS will buy just 31% of what was ordered this year
- Meanwhile, INSABI will now buy patented or single-source medicines, which were previously handled by UNOPS

INDUSTRY IMPLICATIONS

- Failings of the current UNOPS procurement mechanism for the country is posing increasing complexity for industry players
- Outside the UNOPS procurement process, product "availability" and "security of supply," have become (and will continue to be) a priority concern alongside price in negotiations with wholesalers and distributors on behalf of manufacturers for INSABI and the other public Social Security Institutes purchasing medical supplies independently

ADDITIONAL RESOURCES

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UNOPS

EL PAIS

Poland experiences first flu season where free flu vaccines are available to all adults

DETAILS

- Lack of available funding in Poland has been the main reason for the absence of wider adult vaccine coverage, but in November 2021, a free vaccination campaign against influenza was initiated
- All persons aged 18 and over are now able to take advantage of the free vaccination – until this time, the only persons entitled to free influenza vaccines were medics, pharmacists, teachers, soldiers and seniors
- The vaccine prescription is most often issued by the family doctor, who usually carries out the vaccination; therefore, family doctors play a key role in advocating for influenza vaccination

INDUSTRY IMPLICATIONS

- Poland is a country with one of the lowest influenza vaccination coverage rates among the EU member states, but the ongoing COVID-19 pandemic has increased the awareness of the Ministry of Health of the need to protect adult cohorts against respiratory disease
- Typically, there has been thinking (among both Polish physicians and the population) that vaccinations solely happen in childhood; doctors need to be made aware of the advantages of adult vaccination before they can even prescribe
- Moving forward, manufacturers need to help raise awareness with prescribers to help boost the uptake of vaccines (whether they are free vaccines or 50% reimbursed) in the adult Polish population

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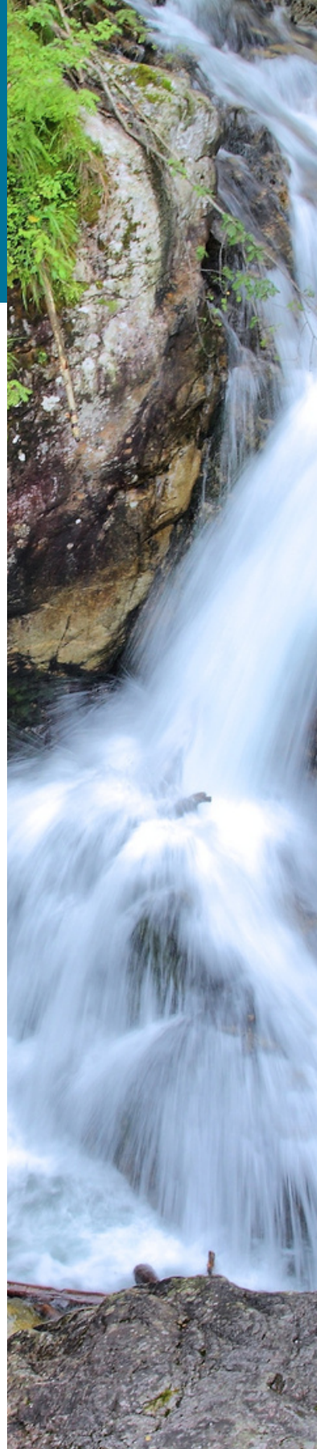
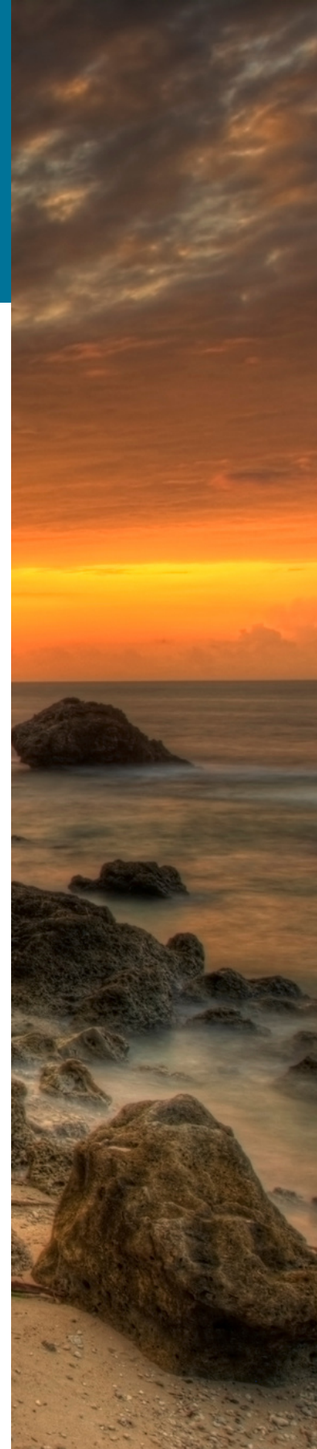
SZCZEPIENIA



Representatives of manufacturers put forward recommendations to the Taiwan Ministry of Health & Welfare (MOHW) & the National Health Insurance Administration (NHIA) on improving managed entry agreement regulation



DETAILS

- The International Research-based Pharmaceutical Manufacturers Association introduced the managed entry agreement (MEA) concept to Taiwan in May 2016
- Over the following two years, industry representatives held numerous rounds of discussions with officials from the MOHW and the NHIA on how to best implement such risk-sharing methods in Taiwan
- Finally, in August 2018, the MOHW formally announced the setting of guidelines for entering into MEA schemes under NHIA reimbursement provisions
- Under the current scheme, the NHIA has proposed multiple options under the MEA umbrella including a combination of class budget cap and price-volume agreements (PVA)

INDUSTRY IMPLICATIONS

- The new recommendations expected soon are anticipated to impact on industry as follows:
  - Evidence-based budget threshold calculation will be by mutual agreement
  - Revision of the 100% clawback provision
  - Initiation of a face-to-face negotiation mechanism to facilitate mutuality in the formation of agreements
  - In order to adhere to the principle of “voluntary MEAs” as set out in the current NHI reimbursement provisions, MEA schemes should only be implemented when they are proposed by the manufacturers and agreed to by the NHIA

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AM CHAM TAIWAN

The Turkish Pharmacists Association calls for drug pricing to be conducted in line with economic reality

DETAILS

- Drug shortages in the country are being blamed on an inflexible pricing system for medicines that exposes operators in the supply chain to losses from the lira's decline in value
- A reference pricing system is used, whereby the least expensive ex-factory price in one of the listed EU countries is taken as the ex-factory price in Turkey; the currency is then converted into Turkish liras at a fixed value every year (not affected by fluctuations in exchange rates)
- However, the government sets this annual rate at a level lower than the actual exchange rate, resulting in prices considerably lower than the respective EU country reference price
- In February 2021, officials set the rate at 4.57 liras per euro, roughly 60% below the then value of 11.27 liras
- In February 2022, the rate was set at 6.29 liras (37.43% rise from last year) – a move welcomed by the Turkish Pharmacists Association

INDUSTRY IMPLICATIONS

- The exchange rate mechanism makes imports punishingly expensive for most suppliers – a drug priced at 10 euros in Greece can sell for as little as 1.8 euros in Turkey
- On the other hand, the current system is beneficial for citizens as co-payments are low (set as a percentage of the drug price); if the exchange rate is adjusted upwards to reflect more fairly the actual exchange rate, drug prices increase and as such so do patient co-payments

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BLOOMBERG

ICLG

Lumykras (sotorasib) is the first drug to complete the UK's Innovative Licensing and Access Pathway

DETAILS

- The UK's Innovative Licensing and Access Pathway (ILAP), first launched in January 2021, aims to accelerate the time to market facilitating patient access to all innovative medicine products, through enabling companies to engage with key regulatory bodies at an earlier stage
- Amgen's Lumykras is the first drug to complete the UK's ILAP and receive a positive recommendation from NICE
- Lumykras will be prescribed as a second-line treatment of mutation-positive locally advanced or metastatic non-small cell lung cancer in patient who have failed to respond to chemotherapy
- Lumykras is approved for use in the Cancer Drugs Fund (CDF) to enable "further direct comparative data, long-term evidence and information around cost effectiveness" to be collected and reassessed
- In addition, Lumykras was the second drug to receive marketing authorization in the UK through Project Orbis, an accelerated oncology pathway, which brings together the UK Medicines and Healthcare Regulatory Agency with counterparts in US, Canada, Australia, Switzerland, Singapore and Brazil

INDUSTRY IMPLICATIONS

- Mechanisms of support for manufacturers include advising on clinical trial designs to streamline the efficient development of evidence required for HTAs, expedited licensing and access routes, and assistance throughout the ILAP process
- NICE reform will seek to secure earlier patient access to valuable innovative therapies, more equitable access to treatments for severe diseases, greater predictability of HTA outcomes and increased use of a broader evidence base, including real-world evidence
- The UK gained access to Lumykras 4 months before the rest of the EU; it remains to be seen if this level of assistance for innovative medicines will increase patient access to other medicines

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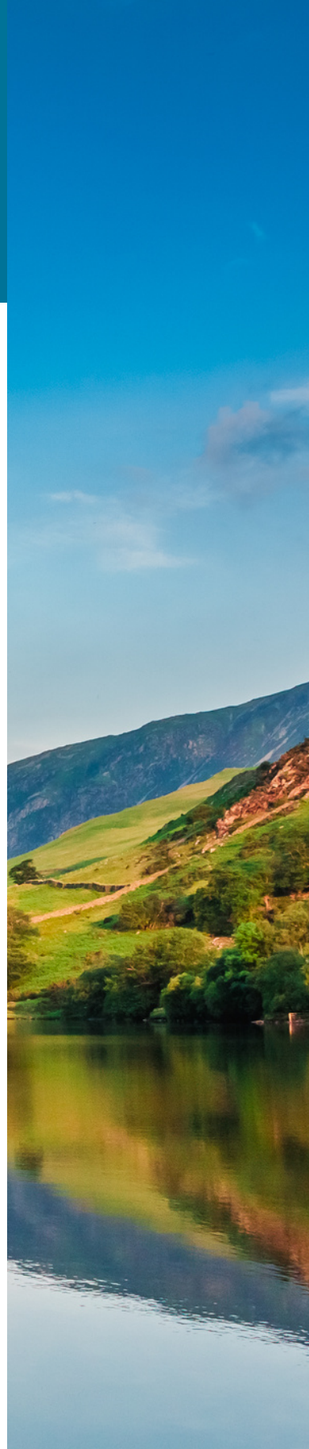
NICE CANCER DRUG FUND

NICE ILAP



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