Windrose Consulting Group Global News Roundup: Q1 2023


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- This edition of the Windrose Consulting Group Global News Roundup: Q1 2023, covers Life science industry highlights from:
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  - Japan
  - South Korea

William Noumba

Major pharmaceutical companies are starting to deprioritize launches in Europe, particularly in Germany

DETAILS

- Bayer has announced a shift of focus of its pharmaceutical business to the US and away from Europe and the UK,
- The head of the German conglomerate's drugs business the Financial Times that core European markets were becoming "innovation unfriendly" through such measures as the expansion of medicines levy in the UK and more restrictive G-KV reimbursement laws in Germany
- Similarly, following European approval for Opdualag (a treatment for melanoma) last September, Bristol Myers Squibb has decided not to launch the drug in Germany due to pricing pressures
- The pharma giant "sees no possibility to achieve a benefit rating from the G-BA" which means the product's price will be 10% less than its branded comparator, thereby greatly limiting the commercial viability of the treatment

INDUSTRY IMPLICATIONS

- With demand for health care outpacing expectations as a result of the Covid pandemic and ageing populations, as well as the war in Ukraine continuing to drive up prices, national budgets in Europe are more constrained
- As a result, negotiations with HTA bodies are increasingly lengthy and willingness-to-pay for new innovative treatments is decreasing
- Therefore, manufacturers may need to initially deprioritize launches in Europe for products with limited comparative data and positive differentiation given the limited price potential
- Instead, they could use patient utilization data once those products are commercialized in the US/RoW to generate longer-term real-world evidence and potentially support a more favorable HTA review in European markets down the line

ADDITIONAL RESOURCES

- Click on the buttons to view

FINANCIAL TIMES

ENDPOINT NEWS

Daisy Pharoah

Pharmaceutical disinvestment in the UK under intensified criticism of Voluntary Scheme for Branded Medicines and Access (VPAS)

DETAILS

- Two major US pharmaceutical companies, AbbVie and Eli Lilly, have left the UK's Voluntary Scheme for Branded Medicines and Access (VPAS)*
- VPAS is an agreement with the government and the NHS in England which limits the profit manufacturers can make on branded drugs sold to the NHS
  - The growth rate of branded drug spend is capped at 2% per year, with industry required to pay rebates on any sales over the capped amount
- Following two successive years of unusually high branded medicines sales (largely resulting from COVID), the VPAS repayment rate increased from 15% to 26.5% at the beginning of 2023
  - Manufactures of branded medicines participating in VPAS will be required to return around £3.3bn in sales revenue to the government this year; an increase versus 2022 (£1.8bn) and 2021 (£0.6bn)
- AbbVie and Eli Lilly both say VPAS has "harmed innovation" and made it "increasingly difficult" to advocate for the UK market to shareholders

INDUSTRY IMPLICATIONS

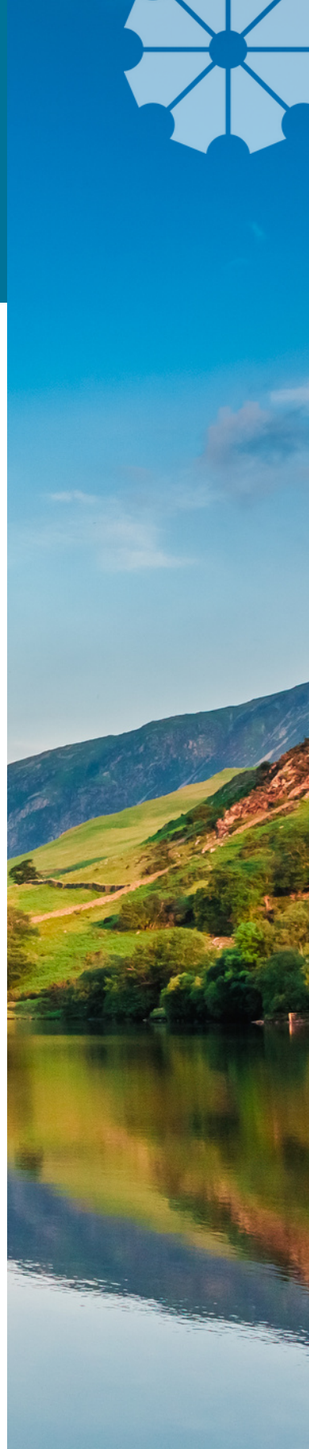
- The steep VPAS repayment rate places the UK out of step with its global competitors
- The move by AbbVie and Eli Lilly highlight growing concern among the industry around the attractiveness of the UK market and concern that VPAS is damaging the UK life sciences industry
- It will be interesting to see whether other manufacturers of branded medicines follow suit and withdraw from VPAS
- Is there potential for manufacturers to cease selling in the UK altogether if the margins available are no longer commercially viable?
- More broadly, it will be interesting to see whether the UK make any changes to VPAS, to prevent erosion in the pharmaceutical sector which could ultimately compromise access to medicine for patients

**The two companies will now fall under the alternative Statutory Scheme for Branded Medicines, which is imposed by the government by law rather than negotiation*

ADDITIONAL RESOURCES

BMJ

PHARMAPHORUM



Paige Stitzel

System Reforms Significantly Impact Commercial Opportunity for Pharmaceutical Products in Germany

DETAILS

- In October 2022, the German Federal Parliament adopted the Financial Stabilization of Statutory Health Insurance System Act in order to help tackle the country's economic deficit
- Key policy updates include AMNOG rebate negotiations, which will give the GKV-SV greater influence in price negotiations, increasing the threshold of added benefit required to receive a premium and limiting the price of products given a no added benefit rating
- Additionally, the sale threshold in which orphan drugs become subject to the AMNOG evaluation process has decreased from €50 million to €30 million per year, with only the first indication automatically granted additional benefit
- A 20% discount will also be included in the AMNOG rebate negotiations for brand-brand combination products, though combination therapies that receive a major or considerable added benefit rating are excluded

INDUSTRY IMPLICATIONS

- While previously able to enter price negotiations given a minor and unquantifiable added benefit rating, manufacturers can now expect a parity price vs. a branded comparator; additionally, manufacturers are now guaranteed at least a 10% discount vs. non-generic competitors given a no added benefit rating
- Therefore, it will be increasingly important for manufacturers to achieve a major and considerable added benefit rating, which includes significant efficacy and safety evidence, in order to obtain a premium price over branded therapies
- By reducing the orphan drug sale threshold, the number of rare disease therapies that qualify for AMNOG evaluation will increase, thus resulting in a higher risk of assessment and potentially negative implications on price given evidence limitations of these products
- Manufacturers can also expect a decrease in price margins for brand-brand combination drugs given the additional rebate in AMNOG negotiations, thus potentially decreasing net profits

ADDITIONAL RESOURCES

FEDERAL MINISTRY OF HEALTH

Jude Barodi

The UK will soon look to the foreign leading regulatory authorities to accelerate marketing authorization

DETAILS

- The European Commission Decision Reliance Procedure (ECDRP), which was introduced to allow the Medicines and Healthcare products Regulatory Agency (MHRA) to fast-track approval for products already approved by the European Medicines Agency (EMA), has been extended until the end of 2023 after having been set to expire at the end of 2022
- The ECDRP allowed manufacturers to obtain marketing authorizations from the MHRA no later than 67 days following a positive opinion ranking from the EMA's Committee for Medicinal Products for Human Use (CHMP)
- Upon expiry of the ECDRP in January 2024, manufacturers will be able to apply for fast-track approval through a new international recognition framework (IRF), which is said to reference marketing authorization decisions already made by the EMA and other leading regulatory bodies
- The aim of the new IRF procedure is to increase the breadth of decisions from regulatory agencies that the MHRA will consider in its own fast-track review (i.e., beyond just the EMA), which in theory will increase market access opportunities within the UK

INDUSTRY IMPLICATIONS

- By considering marketing authorization decisions made by regulatory bodies such as the EMA, FDA, etc., the MHRA can continue to provide fast-track approval for products, further increasing strides made by the ECDRP in reducing time-to-access for pharmaceuticals in the UK following their departure from the EU and the EMA
- In addition to reducing time to authorizations, new access routes will be paved as products will increasingly be able to obtain authorizations in the UK based on decisions in other markets; approval abroad may make approval within the UK significantly quicker
- However, manufacturers may begin to prioritize approval in markets the new IRF references decisions from – moving the UK down in launch order considerations given that approval in the UK may hinge on foreign decisions
- This likely increase in ease of access and decrease in time to approval will improve access to coveted therapies as they emerge globally for patients of high-unmet need areas in the UK

ADDITIONAL RESOURCES

GOV.UK

GOV.UK

Colin Banks

Spain will soon require manufacturers of all new medicines to submit economic evaluations

DETAILS

- An advisory member of the Direccion General de Cartera Comun de Servicios del SNS y Farmacia, responsible for the pharmacoeconomic evaluation of the IPT process, Spain will soon require manufacturers to provide health economic evaluations
- For new active substances, combinations or indications, companies would have to submit a health-economic evaluation (HEE) and budget impact analysis (BIA) along with their value dossier
- The goal is to ensure all new medicines have an economic evaluation within 5 years

INDUSTRY IMPLICATIONS

- The objective is to guide decision-makers on the ICER of the innovations, speed up its own HTA process, and inform budget impact to help inform P&R
- Details remain to be finalized regarding the guidelines stipulating the characteristics of these evaluations (e.g., what comparators will need to used, cost assumptions)
- However, the new focus on cost-effectiveness has potential to significantly limit drugs' pricing potential, as it aims to contain healthcare spending and promote "rational use" of medicines

ADDITIONAL RESOURCES

DIARIOFARMA

Amy Morgan

Universal Health Coverage for India was envisioned to be implemented by 2022, however the country is yet to ensure healthcare for all

DETAILS

- In 2018, given high OOP spending in India, the Government launched the health insurance policy Pradhan Mantri Jan Arogya Yojana (PMJAY), under the Ayushman Bharat scheme
- However, today there remains virtually no insurance product available for out-patient care, including in PMJAY, to help improve financial protection
- Health insurance coverage among households from any source stands at 41%, less than in many developing countries
- There is substantial state variation as on the one hand Rajasthan (88%) and Andhra Pradesh (80%) stand at the top, on the other hand, Bihar (17%) and Uttar Pradesh (16%) stand at the bottom in terms of coverage of health insurance (the districts within states are also experiencing huge variations)
- India is now committed to attaining Universal Health Coverage (UHC) by 2030

INDUSTRY IMPLICATIONS

- Pharmaceutical manufacturers wishing to gain public market access in India face protracted and fragmented reimbursement negotiations with heavy downward pressure on price
- Coverage under any health insurance scheme for outpatient products remains virtually non-existent
- As such, manufacturers are faced with the need to address affordability barriers through novel Patient Affordability Schemes (e.g., microfinancing, loyalty and/or donation programs)

ADDITIONAL RESOURCES

THE PIONEER

Amy Morgan

Rare Disease drugs continue to struggle to gain entry to the National Reimbursement Drug List (NRDL)

DETAILS

- In January 2023, China's National Healthcare Security Administration (NHSA) published the 2022 National Reimbursement Drug List (2022 NRDL), imposing a comparable level of pricing discounts to those seen in previous rounds
- There were a total of 19 rare disease drugs eligible for NRDL negotiation, but only seven were ultimately successful
- After the negotiation, the following rare disease drugs entered the 2022 NRDL:
  - Lanadelumab (Takeda): HAE
  - Risdiplam (Roche): SMA
  - Dimethyl Fumarate (Biogen): MS
  - Ofatumumab (Novartis): MS
  - Inebilizumab (Horizon Therapeutics): NMOSD
  - Riluzole (Zhaoke Pharma): ALS
  - Treprostinil (Zhaoke Pharma): PH
- However, the prices of the drugs included on the NRDL are significantly lower than prices in other markets
- Once included in the NRDL, these products set the pricing benchmark for following products in the indication i.e., one year after the 95% discount of Spinraza, its competing product Risdiplam is included, reportedly with a discount of 94%

INDUSTRY IMPLICATIONS

- Pharmaceutical profit-margins in China have been facing challenges under current NRDL practice as substantial levels of discount appear to be necessary to be included
- Industry observers of the Chinese pharmaceutical market note that the health insurance system is not well adapted to orphan drugs as it is designed to provide basic coverage
- For manufacturers of high-cost therapies, notably orphan drugs, given the structural constraints of the Chinese market, the trade-off between profitability and sales volume will continue to be a major product launch decision for each company
- In lieu of NRDL coverage, manufacturers will need to consider alternative access and funding such as commercial health insurance, innovative payment schemes and the more traditional Patient Assistance Programs (PAPs)

ADDITIONAL RESOURCES

NHSA

Amy Morgan

After more than 100 successful lawsuits from families forcing the Brazilian public health system to pay for treatment, the government announced that it would begin covering Zolgensma by default for infants with the most severe cases of SMA later in 2023

DETAILS

- Zolgensma received Brazilian marketing authorization for the treatment of spinal muscular atrophy in August 2020
- Due to the lack of convincing evidence to support the added therapeutic benefit of Zolgensma over existing alternatives, the Brazilian drug pricing authority approved a maximum price that was 77% lower than the intended manufacturer's price
- Consequently, Novartis decided not to commercialize the therapy in Brazil
- More than half of the population in Brazil rely on the public health system; families seeking Zolgensma tried to raise funds through crowdfunding, but most often they turned to the courts in a process "judicilizacão"
- The result is that the courts have obliged the Ministry of Health to fund Zolgensma citing the right to health legislation

INDUSTRY IMPLICATIONS

- Brazil's experience with Zolgensma demonstrates the challenges posed by the monumental prices of the emerging gene therapies to governments and insurers with limited budgets in resource-constrained health systems
- These challenges are set to multiply in coming years as more such treatments become available for larger groups of patients
- New gene therapies run counter to traditional payment models where costs and benefits are typically spread over annual cycles; payers are wary of the true patient health benefit due to high upfront costs for savings realized over the patient's lifetime
- The objective for manufacturers will be to work with payers to develop innovative payment structures not only to mitigate the risk concerns of covering one-time gene therapies, but also how to alleviate upfront costs

ADDITIONAL RESOURCES

BMJ GLOBAL HEALTH

Amy Morgan

The JPMA, PhRMA and EFPIA have requested that patented medicines be excluded from the FY2023 Central Social Insurance Medical Council NHI Drug Price revision in the current challenging economic

DETAILS

- Biennial price revisions have operated in Japan for a number of years - cutting prices in April of every other year based on a survey of the differential between NHI reimbursement prices and actual procurement prices
  - Medical institutions are permitted to retain this differential which can be a significant source of revenue for them
  - The government seeks to control pharmaceutical expenditure by narrowing the acceptable discount allowance to 2% and cutting the prices of drugs that have larger margins
  - In April 2022, the average price cut was ~6.7%
- Maintaining drug prices during the patent period is the standard practice in major developed countries, as such there is concern that access to new innovative medicines may be impaired by the declining attractiveness of the Japanese market
- The country is experiencing “trends of drug lag,” as approvals decrease; to combat this, the Sakigake designation system of priority consultation, assessment, and review for certain pharmaceutical products, has operated as a pilot since April 2015

INDUSTRY IMPLICATIONS

- The off-year drug price revisions will be rolled out in April 2023 and will likely lead to downward pricing pressure for manufacturers
  - It is predicted to result in additional price cuts to 48% of listed products across multiple therapeutic areas
  - Stakeholders emphasize that price revisions should be targeted only for “products with large discrepancies” rather than maintaining a standardized formula
- However, to compensate, the MHLW has also approved policies that are expected to incentivize innovation in high unmet need therapeutic areas
  - As part of this, the MHLW intends to expand both its Orphan Drug Designation program as well as the Price Maintenance Premiums scheme

ADDITIONAL RESOURCES

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INTERNATIONAL TRADE ADMIN

Amy Morgan

South Korea rolls out new access and evaluation rules for high-value, one-shot (curative) drugs

DETAILS

- In response to the increasing social demand for prompt insurance coverage for new drugs for high-value serious diseases*, there are plans to pilot a system that combines the evaluation of drug benefits and the negotiation of drug prices at the same time as the Ministry of Food and Drugs approval process
- In addition, the Ministry of Health and Welfare (MoHW) has specified three types of risk-sharing contracts applicable to high-value, one-shot, curative treatments
- Pharmaceutical companies will also be re-evaluated for clinical utility and cost-effectiveness in the fourth year after listing and may be subject to price revision

INDUSTRY IMPLICATIONS

- As more and more expensive cell and gene therapies enter the South Korean market, the government has begun to feel the budgetary burden
- Manufacturers will be subject to increasing pressure in negotiating risk sharing agreements, as well as to justify their long-term value
- To start this process, the MoHW has specified three types of risk-sharing applicable for high value, one-shot curative treatments:
  - Reimbursement type - A percentage is reimbursed by the pharmaceutical company to the National Health Insurance Services
  - Capped type - If the actual spend exceeds the pre-set annual spend total (CAP), a certain percentage of the excess will be refunded
  - Patient-based performance-based - Follow-up of each patient's treatment performance for a total of 5 years, and every year there is potential for a certain percentage refund in case of treatment failure; consent for long-term follow-up must be obtained, including periodic response evaluation

**There is no internationally agreed definition of 'high-value drug', but it has been defined as a drug that requires price control and long-term effect confirmation due to high price and uncertainty of effectiveness*

ADDITIONAL RESOURCES

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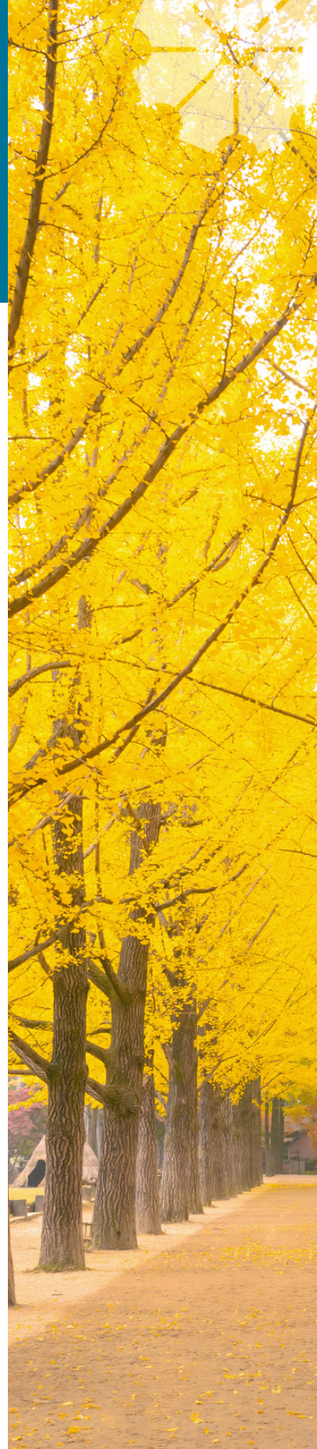
MOHW



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