HPR85
SOCIOECONOMIC IMPACT OF REVERSE SWITCHING OVER-THE-COUNTER (OTC) ANTIFUNGAL AND ANTIVIRAL MEDICINES TO PRESCRIPTION ONLY MEDICINES (POM)

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Objectives: The European Commission has developed a new proposal for its pharmaceutical legislation framework, including an amendment to Article 51, classifying all antimicrobials as prescription-only medicines (POMs) to reduce antimicrobial resistance (AMR). This proposal is logical for antibiotics but risk of such in antivirals and antifungals is less obvious where resistance risk is mainly linked to high-dose, long-term, and systemic use in immunocompromised patients. In addition, economic impact on self-manageable conditions (athlete's foot, cold sores, and vaginal thrush), currently treatable with topical OTCs has not been considered. This research evaluates the socioeconomic and health consequences of reclassifying OTC antifungal and antiviral. ***Methods:*** A decision tree model was developed using epidemiological and surveillance data, retail sales data, social media insights, patient surveys, and peer-reviewed literature. The model assumed that if the products were restricted to POMs patients would either do nothing, seek alternative treatments, or obtain a prescription through doctor's appointments. The model estimated both direct and indirect costs, considering the impact on healthcare resources due to hospital visit, delayed treatment, and productivity losses across 19 European countries. ***Results:*** Around 48 million additional doctor's visits and 12 million emergency visits are estimated to occur in symptomatic individuals who rely on OTC antifungals and antivirals across 19 countries per year. Total cost is expected to increase by €13 billion from healthcare related spend (€10 billion) and Productivity loss (€3 billion). Patients with vaginal thrush would have the highest additional outpatient visits compared to other indications with total cost of €6 billion. ***Conclusions:*** The proposed reclassification is expected to significantly increase healthcare costs and lead to worse health outcomes, as delayed treatment could exacerbate health conditions. A targeted approach with focus on reclassifying specific products which have an increased risk of AMR development while maintaining access to treatments for self-manageable conditions is recommended.

HPR86
FREQUENCY AND VARIATION OF CLOCK-STOP DURING EMA ASSESSMENT FOR ONCOLOGY PRODUCTS: IMPLICATION ON JCA TIMELINES

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Objectives: The implementation act adopted for HTA regulation defined the timelines of scoping, submission and assessment and output of Joint Clinical Assessment (JCA), which will be in parallel with the European Medicines Agency (EMA) timelines. This study aims to understand the variation on company response times and the potential influence from JCA dossier submission, by analyzing the breakdown of the current EMA review cycle time, frequency and variation of clock-stops in the approval process of oncology new active substances (NASs) ***Methods:*** Data was extracted from EMA reports from oncology NASs approved between 01-Jan-2019 to 31-Dec-2023. Review time is calculated by start of scientific assessment to the outcome letter, clock-stop time was calculated as the timing between the release of outcome letters and the response from sponsors from oncology NASs approved for each cycle of communication. ***Results:*** The first and second clock-stop occurred in 100% (n=83) of the oncology products approved, while only in11% of these products more than 2 clock-stops were needed. The time for the first scientific assessment for standard reviews showed median of 119days and a median of 89 days for accelerated reviews. The first clock-stop had a median duration of 77 days, with a variation ranging from 50 days (25th percentile) to 97 days (75th percentile), followed by the second scientific assessment (median 63 days). ***Conclusions:*** Our analysis showed that all oncology products utilized both the first and second clock-stops, with additional clock-stops being rare. The JCA submission is due 100 days after the initial JCA sub-group request, which follows the JCA scoping expected 10 days post first scientific assessment. Consequently, JCA submission may coincide with or follow the first clock-stop phase. Preparing for JCA might affect the company's response time to EMA queries. This study offers a baseline to assess changes in the regulatory review process post-HTAR implementation.

HPR87
POLAND'S MEDICAL FUND ACT: PROGRESS OF THE NEW FAST-TRACK TLI REIMBURSEMENT PATHWAY

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Objectives: To evaluate the progress of the new 'fast-track' TLI reimbursement pathway introduced in Poland's 2020 Medical Fund Act. ***Methods:*** Data was gathered on the number of therapies recommended for inclusion in the high-level pharmaceutical technology innovation (TLI) list by the Agency for Health Technology Assessment and Tariff System (AOTMiT) in 2021-2024, the number chosen for the final annual lists by the Ministry of Health (MoH), and the number eventually gaining reimbursement, in order to assess the progress of the 'fast-track 'reimbursement pathway and its contribution to improving access to new orphan medicines. ***Results:*** Of the 44 medicines included by the AOTMiT in its draft TLI lists in 2021, 2022, 2023 and 2024, 70.5% were orphan drugs. The MoH selected 25 of these 44 medicines – or 56.8% – for the final TLI lists; 22 of these (88%) were orphan drugs. Only 14 of the drugs selected by the MoH for the final TLI lists have gained reimbursement through the TLI pathway, or 56%. One of the drugs selected for the TLI list gained reimbursement through the standard procedure, meaning that the total number of TLI-listed drugs to gain reimbursement is 15, or 60%, of which 12 (80%) are orphan drugs. However, these 15 account for only 34% of those drugs recommended by the AOTMiT for TLI listing. ***Conclusions:*** This research indicates thatthe 'fast-track' TLI mechanism has helped to speed up and improve access to orphan drugs in Poland, but there remains widespread dissatisfaction at the limited number of therapies progressing to reimbursement under the much-vaunted system. Additionally, concerns over potentially punitive regulations applying at the end of reimbursement terms, and the AOTMiT's data collection process accompanying TLI drugs, may be discouraging manufacturers from submitting reimbursement applications.

HPR88
REVOLUTIONIZING MARKET ACCESS: AI-DRIVEN PRICING STRATEGIES IN THE PHARMACEUTICAL INDUSTRY

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Objectives: Rising cost pressures and advancements in Machine Learning (ML) technologies accelerated the use of Artificial Intelligence (AI) in the pharmaceutical industry. By harnessing the power of AI, pharmaceutical companies can potentially address pricing and reimbursement challenges, while seeking innovative approaches to enhance Market Access (MA) and develop pricing strategies that optimize patient access. This research assesses how AI can drive peri-launch pricing strategies for pharmaceuticals, delving into the potential transformation of pricing frameworks within the healthcare industry. ***Methods:*** Secondary research from 2019 to 2024, including industry reports and whitepapers, was conducted to gather insights on AI's use in drug pricing. ***Results:*** We have identified five key areas where AI solutions have showcased benefits within pharmaceutical pricing:

- Dynamic Pricing Algorithms:adjust pricing in real-time based on market demand, competitor pricing, and product differentiation, optimizing competitiveness.
- Value-based Pricing Models:assess a drug's value through clinical efficacy, patient outcomes and economic impact, facilitating fair pricing.
- Segmented Pricing Strategies:analyze the macro-economic environment and market data to identify needs and willingness to pay, enabling customized pricing strategies.
- Optimized Negotiation Tools:analyze pricing scenarios, regulations, and market dynamics, providing recommendations for optimal pricing negotiations with payers.
- Real-time Competitive Intelligence Solutions:monitor competitors' pricing strategies in real-time, enabling proactive competitive pricing decisions.

Conclusions: AI-driven pricing strategies support pharmaceutical companies in optimizing pricing, considering market dynamics. However, the AI role in clinical benchmarking for pricing decisions is uncertain. Robust clinical evidence, including comparisons with standard of care is crucial in determining therapy prices, with Health Technology Assessment (HTA) agencies scrutinizing clinical data uncertainty prior to pricing negotiations. MA organizations can effectively support pricing optimization strategies, linking clinical data with economic value, by determining early in the development cycle the key parameters influencing the economic value, while maintaining regulatory compliance and transparency, to enhance patient access and meet payer needs.

HPR89
IS CHINA BECOMING MORE ATTRACTIVE TO MANUFACTURERS OF INNOVATIVE MEDICINES? INSIGHTS FROM THE BOAO MEDICAL PILOT ZONE

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Objectives: Since 2018, medicines approved by regulators outside of China such as the Food and Drug Administration (FDA) can be used in China's Boao Lecheng International Medical Pilot Zone, if approved by the Hainan authority. In 2019, the Implementation Plan for the Clinical Real-world Data (RWD) Application Pilot was also introduced to facilitate RWD generation in Boao. This research examines the statuses of Boao-authorized medicines to evaluate how this pathway can support both National Medical Products Administration (NMPA) regulatory approval in China as well as National Reimbursement Drug List (NRDL) listing and public reimbursement. ***Methods:*** Information of Boao-authorized medicines and insurance coverage was extracted from the Lecheng Administration Bureau's website and official WeChat account (31-Oct-2023). Regulatory information was extracted from the NMPA website (31-Oct-2023). Information of NRDL inclusion was extracted from the National Healthcare Security Administration (NHSA) website (13-Dec-2023). ***Results:*** 101 medicines have been authorized for use in Boao. 45/