and Reimbursement Committee) assessment. A 24-month contract with an ex-factory price (PP) equal to X EUR per dose and a transfer price to the National Public Health System (NPHS), following application of a confidential discount for public structures (-X%), of X EUR per dose. After 24-months, an analysis of VBMEA is carried out. The price of the MP is therefore established based on AIFA registries and VBMEA results. The cost value incurred by the NPHS, intended as the difference between the price in market (entry) access phase and the price negotiated (PVB) in the light of the VBMEA results, shall be returned by the pharmaceutical company in the form of a payback.
Conclusions. Currently, MEAs represent one of the main topics of discussion between the European National Payers Authorities. There is very little information on product performance that results from MEAs. This research project could provide advice to policy makers to decrease negotiation time by ensuring earlier access to innovation for patients.

PP14 Value-Based Pricing For Advanced Therapy Medicinal Products: Emerging Affordability Solutions

Elisabete Gonçalves (elisa.nunes.goncalves@gmail.com)

Introduction. The emergence of advanced therapy medicinal products (ATMPs), a disruptive class of health technologies, is generating important challenges in terms of value assessment, and their high prices introduce critical access and affordability concerns.
Methods. The aim of this oral presentation is to expose the challenges of traditional value assessment and pricing and reimbursement methods in the evaluation of ATMPs, and to characterize the current and prospective financing solutions that may ensure patient access to and affordability for these health technologies.
Results. Standard health technology assessment (HTA) is not designed for assessing ATMPs and may delay access to these therapies; thus, a broader concept of value is required. As a result, value-based pricing methodologies have been gaining prominence as a way to cope with the specific challenges of ATMPs. The pricing and reimbursement framework should ensure a balance between encouraging innovation and maximizing value for money for payers through the attribution of a fair price to new health technologies. The provision of early scientific advice to developers by regulatory and HTA bodies is key, as it will help diminish the perspective gap between developers, regulators, and payers.
Conclusions. The high efficacy and high price dynamic of many ATMPs necessitates novel financing models, both in the European Union and in the USA. Managed entry agreements, where financing is conditional upon the submission of additional evidence, linked with leased payments may offer effective strategies to address the uncertainties caused by the evidence gap associated with ATMPs, ensuring affordable and sustained access to these therapies.

PP15 The National Pricing And Reimbursement Process In China, A 2021 Update

Xirong Song (xirong.song@globalpricing.com), Shahela Kodabuckus and Preeti Patel

Introduction. The Chinese National Reimbursement Drug List (NRDL) was established in the early 2000's and includes the drugs both fully and partially covered by National Basic Medicine Insurance. As China's health system has been reformed over the past decade, it is important for manufacturers to understand the ever-changing reimbursement process and its implications on newly launched drugs. This study provides an updated overview of the process based on research conducted in 2021.
Methods. Targeted secondary research was undertaken to evaluate the pricing and reimbursement landscape in China. Primary research was conducted to assess the perspectives of three payers and one policy expert.
Results. National listing remains the most viable and exclusive pathway to get a product reimbursed by public health insurance in China. Since 2017, the NRDL has been updated annually, and revisions are managed by the National Healthcare Security Administration (NHSA). Insights from 2021 suggests that the process of listing a new product on the NRDL lasts five months (July to November). Manufacturers should ensure that submissions are made when the annual NRDL process formally begins, and clinical and health economic evidence is compulsory. If a successful opinion is made by the assessment board, the manufacturer will be invited to negotiate a price with the NHSA. Data from the NHSA indicated that a total of 704 applications were made in 2020. In addition, 138 exclusive drugs were eligible for price negotiation, of which 96 drugs were successful and added to the NRDL. Findings also suggested that the average discount rate increased from 44.0 percent in 2017 to 50.6 percent in 2020.
Conclusions. The national reimbursement process in China has become more transparent overtime. Even so, NRDL listing remains a challenge, with decisions driven by clinical and pharmacoeconomic evidence, and price. Significant price cuts should be considered and anticipated to ensure successful negotiation outcomes.

PP16 Machine Learning In The Treatment Of Spinal Deformities: Early Life-cycle Economic Analysis In Australia

Rashmi Joglekar (rashmi.joglekar@medtronic.com) and Aaron Shikule

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