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

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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

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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

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Introduction. Patients with spinal deformity require implanted spinal rods to be specifically shaped to their anatomy. Spinal rods which are manually shaped in the operating theatre are prone to fracture and malpositioning. This emphasizes the need for preoperative planning, intraoperative imaging, and accurate shaping of the implant. The application of machine learning (ML) has enabled precision in shaping patient-specific rods, with the potential to reduce adverse events. Our objective is to assess the economic value of this technology, early in its lifecycle, in the context of Health Technology Assessment (HTA) in Australia.
Methods. A budget impact analysis was performed to quantify the economic value of patient-specific spinal rods from an Australian payor perspective. Clinical outcomes were sourced from literature review, and cost inputs were obtained from Medicare, Private Health Data Bureau and Hospital Casemix Protocol Data databases.
Results. Preliminary analysis indicates that a reduction in the rate of revision surgery due to decreased instrument failure results in cost-savings to the healthcare system, despite a higher outlay for the patient-specific rods. Adolescents who may have remained sagittally malaligned after the implantation of manually bent rods are expected to derive the greatest benefit from this ML application. The key uncertainty in this analysis is the limited real-world data of this emerging technology. ML is an iterative process of continuous improvement, identifying correlations within the data collected. As additional surgical data are integrated into predictive models, we anticipate ML technology will enhance decision-making support in surgical strategy and enable better implant precision, resulting in further decreased operating time, reduced mechanical complications, and increased healthcare savings.
Conclusions. ML technology is enabling precision in patient-specific implants, which is expected to drive healthcare cost-savings due to a reduction in instrument failure. Fewer replacement surgeries are an important patient-relevant outcome, especially for adolescents with spinal deformity. This preliminary analysis demonstrates the economic value of ML enabled patient-specific rods to Australian payors, early in its lifecycle.

PP17 Is the PriTec Tool Useful In The Identification Of Disruptive Healthcare Technologies?

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Introduction. A disruptive technology has been defined as an innovation that completely changes the way things are done. Early identification of potential disruptive health technologies has become a key point in the agenda of decision makers and health technology assessment (HTA) bodies. The PriTec tool is an automatically executable web application that was developed in 2009 by the Galician HTA Agency to facilitate decision-making regarding the selection of technologies for post-launch observation. The tool has been updated to allow scoring and ranking of technologies before their introduction into the healthcare portfolio. The aim of this work was to propose a framework for assessing the usefulness of the PriTec tool in relation to identifying possible disruptive innovations.
Methods. To evaluate the applicability of the PriTec tool for distinguishing disruptive from non-disruptive innovations, we selected a few examples from prior acknowledged disruptive and non-disruptive innovations. These technologies were scored against the predefined criteria and the results were compared and analyzed globally and by type of domain. The PriTec tool assesses six domains of technologies: clinical condition, comparative effectiveness and safety, economic impact, implementation consequences, and dissemination speed.
Results. Disruptive technologies (e.g., transcatheter aortic valve implantation or point-of-care tests) had higher weighted global scores than non-disruptive technologies. In the domain analysis, the scores for implementation consequences were higher for disruptive than for non-disruptive technologies. Both types of technologies had similar scores in the other domains.
Conclusions. The PriTec tool seems to be useful for identifying potential disruptive technologies through its implementation domain. Further validation strategies are required to confirm the tool's applicability and to improve its accuracy in the field of health disruption. The tool could be used by governments, horizon scanning organizations, and HTA organizations to promote the evidence-based detection of disruptive technologies in clinical practice. However, it is advisable that the tool be further tested and validated in other contexts.

PP18 Horizon Scanning For Clinical Biosimilar Medicines: Informing The Lifecycle Of Health Technology Assessment And Market Access

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Introduction. The National Institute for Health and Care Research (NIHR) Innovation Observatory (IO) national horizon scanning research centre, has a remit to notify its stakeholders, including the National Institute for Health and Care Excellence (NICE), about innovative interventions; including biosimilar medicines in the pipeline. Biosimilar medicines bypass many developmental steps, making them substantially cheaper to manufacture for providers, which increases market availability and improves treatment access for patients.
Methods. Since 2017, the NIHR IO has monitored biosimilars in clinical development that align to the NICE health technology assessment remit. The data set explored was exported from our internal medicines innovation database - MInD.

Data sets were created that included information on the characteristics of biosimilars and their associated clinical trials. Analyses and visualization creation were carried out using Microsoft Excel and Microsoft Power BI.

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