PHP150
PRACTICAL PROBLEMS OF COMPARATOR SELECTION TO ASSESS COST-EFFECTIVENESS OF NEW DRUGS FOR REIMBURSEMENT DECISION: A QUALITATIVE STUDY IN SOUTH KOREA
Kang H, Lee H, Cho H
Yonsei University, College of Pharmacy, Yonsei Institute of Pharmaceutical Sciences, Incheon, South Korea
OBJECTIVES: Under the positive drug listing system, pharmaceutical companies in Korea are required to provide cost-effectiveness (CE) evidence of newly approved drugs for listing on the National Health Insurance (NHI) drug formulary. It has been argued that selection criteria of comparator treatments suggested by the CE guideline are too limited and unrealistic to conduct a valid CE assessment. Therefore, our study was conducted to investigate types of practical problems in comparator selection in order to improve the validity of CE analysis. **METHODS:** We conducted focus group interviews (FGI) with experts working in research-based drug companies, charged of submitting CE evidence of their products to NHI. Each participant received an interview question via an e-mail beforehand and presented their opinions at round-table discussion. **RESULTS:** Examples of the problems associated with selecting appropriate comparators identified from FGI are as follows: drugs with the same indication, but therapeutically nonequivalent, were used as comparators ; there is no guidance on whether to include off-label drugs as comparators; when off-patent products were selected as comparators, the price of the new drug was compared with the price of generic products rather than the initial price of the original products set during the patent period; it is difficult to obtain reliable market share data needed for selecting a comparator; and the best supportive care was selected as a comparator when there's no appropriate treatment alternatives. **CONCLUSIONS:** We expect that the results of our investigation would contribute to improve the quality of CE guidelines in South Korea as well as other countries, and to improve assessment of the true value of pharmaceutical intervention.

PHP151
BUILDING QUALITY IN HTA PROCESS AND DECISION MAKING: CAN KEY PERFORMANCE MEASURES OF GOOD PRACTICES IN HTA BE IDENTIFIED?
WANG T
CIRS, London, UK
OBJECTIVES: To establish a working definition of "quality" in the HTA context; to identify the key features of good-quality HTA submission and review performance. The outcome of the research will be used to facilitate the development and adoption of best practices in HTA submissions, assessment processes and decision making. **METHODS:** The research was initiated by identifying common elements that underpin a quality submission dossier, and a set of key performance indicators (KPIs) of HTA review processes and procedures. International experts representing HTA/coverage agencies, academics and pharmaceutical companies were invited to discuss the identified parameters from diverse viewpoints. The key discussion points and recommendations for KPIs are outlined herein. **RESULTS:** Four elements of a quality dossier were identified: robustness and relevance of the scientific data; dossier completeness, that is, the inclusion of all relevant information; integrity or consistency; and logical structure and clear format. Quality of HTA review is most easily measured by assessing outcomes of tools designed to ensure or to support good-quality process such as internal and external peer reviews, audits, standard operating procedures and procedures for learning and feedback. Ten KPIs of the HTA review process considered important from a company's perspective were identified as well the four main areas from HTA agencies perspective: timeliness, relevance, credibility and impact. **CONCLUSIONS:** A key outcome of this research was a clear understanding of "quality" in the context of HTA across stakeholders, and the identification of key factors, irrespective of the diversity of HTA agencies, which could be used to measure the quality of process. The next phase of the research will be to develop an instrument to measure quality of HTA process based on identified KPIs and to be piloted and validated by key stakeholders.

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HOW ARE TOPICS SELECTED AND PRIORITIZED BY THE NATIONAL INSTITUTE OF HEALTH AND CARE EXCELLENCE (NICE) AND WHAT MIGHT BE THE OPTIONS IF A TECHNOLOGY IS NOT SELECTED?
Ranson P[1], Cline H[2], Hill CA[1], Hill CE[1], Marshall JD[1], Harries M[1]
[1]*MAP BioPharma Limited, Cambridge, UK,* [2]*Pinsent Masons LLP, London, UK*
OBJECTIVES: In contrast to the Scottish Medicines Consortium, NICE does not evaluate all new medicines, but uses a set of specific selection criteria. Where a technology is not selected for assessment the affected products may face difficulties in achieving payer and physician uptake. We aim to demonstrate and evaluate the difficulties faced by those seeking market access for products and the consequence of non-selection. Whilst oncology products currently have the Cancer Drugs Fund (CDF) to fall back on, there is an issue of how NICE, CDF and NHS England policies will work together in the future. We further consider the possible options, both for delaying and non-assessment, or failure to obtain reimbursement through other routes. **METHODS:** We review the topic selection methodologies and compare the number of marketing authorizations approved in recent years and those products reviewed by NICE. Examples of orphan drugs that have not been selected are provided. We further review opportunities for redress for the manufacturer where they are not subject to a technology appraisal. **RESULTS:** The position of a company seeking reimbursement for a new product that has not been reviewed by NICE is precarious, forcing them to rely on NHS England policies, local commissioner approvals, individual hospitals within CCGs or, ultimately, legal redress. Currently, there are over 20 NHS England policies to support the commissioning of products, and services associated with those products; and over 100 awaiting review. The common characteristic accompanying success is strong clinical support from the relevant NHS England clinical reference group and powerful patient lobbying. **CONCLUSIONS:** The current position, whether caused by delay or a positive decision by NICE not to review, is considered unsatisfactory both for patients and manufacturers. There are several options for remedy such as a more comprehensive product review programme, but this could lead to further delays.

PHP153
ACCESS TO MEDICINE, REIMBURSEMENT AND PRICING IN GERMANY: WHAT ARE THE IMPLICATIONS OF AMNOG?
Mueller E, Schmidt E, Schrank L, Neeser K
LASER ANALYTICA, Loerrach, Germany
OBJECTIVES: Since the health care reform in Germany (AMNOG) in 2011, newly approved drugs have to demonstrate their innovation to avoid reference group pricing. The pharmaceutical manufacturer (PM) has to submit a dossier proving additional benefit versus the appropriate comparator recommended by the G-BA (Joint Federal Committee). **METHODS:** Benefit assessments and G-BA decisions to date were analyzed. Outcome data, indirect comparisons and decisions (until January 2015) were explored with regard to factors potentially impacting the outcome of price negotiations. **RESULTS:** 148 agents entered the assessment process, 102 dossier completed the whole assessment process. G-BA evaluations resulted in 26 minor, 21 considerable, and 55 not quantifiable/no additional therapeutic benefit of assessed vs. comparator drug. In 29 cases the G-BA did not follow IQWiG's conclusions of the extent of additional benefit. The choice of appropriate comparator was controversial between G-BA and PM in 10 cases, followed by questions about evidence of benefit. 5 drugs, which failed to prove an additional benefit, were withdrawn from the German market. In a sub-analysis 18 drugs were examined, where the reimbursed price has been negotiated between the National Association of Statutory Health Insurance Funds (GKV-SV) and PM. The mean rebate was 17% with a range from 0 to 52%. Negotiated rebates were not correlated with any of the clinical and economic parameters (e.g. number of patients benefitting, proposed price) analyzed. **CONCLUSIONS:** AMNOG mediates price control despite mandatory reimbursement of innovative drugs. Following initial pitfalls in dossier development the withdrawal of 5 drugs in 2012 may indicate that nowadays either the PMs are more familiar with AMNOG or, that drugs with limited potential of proving an additional benefit tend to be not launched in Germany. The majority of price negotiations resulted in reductions of < 20%. It was not possible to identify parameters predicting the magnitude of rebates.

PHP154
EVALUATING GLOBAL EARLY MARKET ACCESS OPPORTUNITIES FOR INNOVATIVE THERAPIES: FOCUS ON JAPAN, UK AND US
Carr DR, Anastasaki E, Bradshaw SE
Market Access Solutions LLC, London, UK
OBJECTIVES: Early market access schemes are expanding across the globe, presenting health technology suppliers with a variety of opportunities for expediting product approval. This paper aims to provide an overview of three such schemes: the 'conditional approval' opportunity in Japan's Pharmaceuticals, Medical Devices and Other Therapeutic Products (PMD) Act; the UK's Early Access to Medicines Scheme (EAMS); and the Breakthrough Therapy (BT) designation program in the US. **METHODS:** Secondary research identified market-specific early access schemes and key themes were evaluated. Where available, quantitative data were analyzed. Hypotheses were generated and then validated during in-depth interviews with key stakeholders across markets. **RESULTS:** The US BT designation is the most advanced early access opportunity, having been established in July 2012. Of the 212 technologies reviewed so far, 35% have gained BT status. Through December 2014, 16 have subsequently obtained full approval. Launched in the UK in April 2014, the EAMS has had three promising innovative medicine (PIM) designations, which forms the first of two steps in gaining early market access. In Japan, the conditional approval scheme focuses on regenerative medicines and, while interest is significant, the program is in its infancy, having been formalized in November 2014. **CONCLUSIONS:** Health technology suppliers need to evaluate associated costs and benefits when determining whether any of the early access routes are appropriate for a novel product. One consideration is the type of technology in scope: developers of regenerative cell therapies should consider the Japanese scheme, but will need to leverage local partnerships in order to facilitate access. Another consideration is the costs involved in application, and whether the technology is reimbursed during the program. While products are reimbursed in Japan, UK reimbursement is not guaranteed. The BT program is the most mature and globally recognized of the three, and offers ongoing regulatory support until final marketing authorization.

PHP155
COMPARISON OF HEALTH TECHNOLOGY ASSESSMENT (HTA) RANKINGS BY GERMAN AND FRENCH HTA AGENCIES
Hu I[1], Zheng J[2], Hu XH[2]
[1]*University of Southern California, Los Angeles, CA, USA,* [2]*Celgene Corporation, Summit, NJ, USA*
OBJECTIVES: HTA agencies in both Germany (IQWiG) and France (TC) focus on additional benefits without explicit consideration of cost in their HTA assessment. While the German Federal Joint Committee (GBA) usually commissions IQWiG for the assessment, the GBA makes final decisions on the level of additional benefit provided by a new therapy. We sought to document whether the GBA and TC reached the same rankings for the same drug indication evaluated. **METHODS:** We first searched GBA assessments conducted from August 2011 to July 2014 and then cross checked whether the TC completed its own assessment for the same indication. The GBA classifies additional benefits as "Major, Considerable, Minor, Non-quantifiable, No Benefit, and Less Benefit". For the TC, they are categorized as "Major, Important, Significant, Minor, No Improvement, Do Not Recommend". We also examined the comparators used in the assessments. **RESULTS:** A total of 67 indications were evaluated by both agencies. No indication was awarded "Major" by either agency. For 17 "Considerable" ranking granted by the GBA, 2 were given "Important", 8 "Significant", 6 "Minor", and 1 "No Improvement" by the TC. For 21 "Minor" ranking awarded by the GBA, 1 was considered "Significant", 11 "Minor",