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 J., 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 prove 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, where the position of a member is considered unsatisfactory both for patients and providers. The common characteristic accompanying success is strong clinical support of products, and services associated with those products; and over 100 awaiting approval. We further review opportunities for redress for the manufacturer where they are not subject to a technology appraisal. Results: Examples of the problems associated with selecting appropriate comparators identified from FGI are as follows: drugs with the same generic but not generic products rather than the initial price of the original products; and there is no guidance on whether to include off-label drugs as comparators. We are providing results with the price of generic products rather than the initial price of the original products. Conclusions: We found that it is difficult to obtain reliable market share data needed for selecting a comparator, and the most supportive care was selected as a comparator where there’s no appropriate treatment alternative. 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 the 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 key performance indicators (KPIs) of HTA process and decision making; and to be piloted and validated by key stakeholders. 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 points 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 key issues that define good quality HTA process and decision making. 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, advanced electronic procedures for handling dossiers. A 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 transparency. CONCLUSION: A set of HTA KPIs and their definitions were developed, allowing for the refinement of the ‘conditional approval’ opportunity in Japan’s Pharmaceuticals, Medical Devices and Health Technology assessment process, but this could lead to further delays.

PHP152
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., Cline H., Hill CA1, Hill CE2, Marshall JD, Harris M1

1MAP BioPharma Limited, Cambridge, UK. 2Pfizer 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 consequent lack of data for review. 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 work together in the future. We further consider the possible options, both for delaying and non-assessment, or to fail 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 approved 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 drug not being approved for a new technology that has been assessed for the same indication by NICE is precarious, forcing them to rely on NHS England policies, local commission approval, individual hospitals within CGGs or, ultimately, legal redress. Currently, there are over 20 NHS England policies to support the commissioning of products. We also reviewed the cases associated with the approval or non-approval of 67 drugs. Conclusions: 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 J., Schmidt E., Schrank L, Neesser K
LASER ANALYTICA, Lierach, Germany

OBJECTIVES: With the health care reform in Germany (AMNOG) in 2011, newly approved drugs have been allowed 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. RESULTS: 108 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 assessed vs. comparator drug. In 29 cases the G-BA did not follow IQWiG’s recommendations and selected an alternative comparator for the reimbursement decision. Further, there was a discussion 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 or 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 > 50%. 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 DJ, Anastasiaki 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 Scottish Medicines Consortium, 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, the conditional approval scheme focuses on regenerative medicines and, whilst interest is significant, the attention of existing infant, having been formalized in November 2014. Conclusions: Health technology suppliers should 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 L1, Zheng J2, Liu KH3
1University of Southern California, Los Angeles, CA, USA, 2Colgene, Coromandel, Summit, NJ, USA

OBJECTIVES: HTA agencies in both Germany (IQWiG) and France (TC) focus on additional benefits, or just 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. However, it is unknown whether the GBA assessed 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 identified and analyzed the assessment of 67 drugs approved in 2012 and 2013. Conclusions: The assessment is conducted as described and the associated costs and benefits of each indication were evaluated by both agencies. No indication was awarded “Major” by either agency. For “17 Considerable” ranking granted by the GBA, 2 were given “Insignificant”, 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”, 8 “Insignificant”, and 2 “No Improvement” by the TC.