OBJECTIVES: Gemeinsame Bundesausschuss (G-BA) states that it assesses additional costs of comparator, and clinical grounds, but it also requires that manufacturers submit drug and comparator costs. This raises the possibility that G-BA assessment might be influenced by price, possibly to provide leverage during subsequent price negotiations. This research tests the hypothesis that high cost drugs [relative to the cost of the comparator (therapy)] are likely to receive positive HTA assessment from G-BA.

The following variables were collected from the Federal Gazette publication or the “Beschluss” document: additional benefit assessment, annual cost per patient of drug, and estimated target population. The Scottish Medicines Consortium (SMC) clinical rationale for the same drugs and indications were collected to control for clinical efficacy. After excluding orphan drugs, reviews using best supportive care comparators, and reviews without SMC reviews, 58 reviews remained for analysis. G-BA’s additional benefit assessment variables were compared from least benefit to most. The influence of drug cost relative to the comparator on the G-BA assessment was estimated via an ordered logit model. The model also included controls for (1) the target population and (2) SMC’s clinical assessment.

RESULTS: An increase in the cost difference between the drug and the comparator is estimated to result in a modest, statistically significant increase in the odds of receiving an additional benefit assessment greater than a "no additional benefit" opinion. Our hypothesis is that G-BA is strategically discounting its assessment of relatively high cost drugs. The positive estimated relationship is consistent with manufacturers’ setting higher prices for more beneficial drugs (The data available provide no way to statistically account for this plausible source of endogeneity). Our results provide no support for rejecting the null hypothesis that G-BA assesses added benefit independently of drug cost.

PHP24 DEVELOPMENT OF HTA IN TURKEY

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OBJECTIVES: The aim of this study was to assess the development of HTA in Turkey. In this regard, organizational structures of the Ministry of Health (MoH) and Social Security Institution (SSI) and presentations of first HTA meeting held in April 2014 have been analyzed. RESULTS: There are three main HTA agencies in Turkey. One is under the payer institution called SSI. The HTA committee of the payer is asked to fill the need for NICE criteria to define whether they will be reimbursed or not. In other words, this committee is the major decision HTA committee. Other two HTA committees are under the MoH. One of these is under the General Directorate of Health, and another one is under the Ministry of Science and Technology. This committee assesses certain drugs which are specifically asked to be evaluated by the SSI, MoH or other Ministries. One of the projects completed by this committee is the evaluation of top 100 selling drugs according to the effect of price, regulation, market and quality of the drugs. The second committee of the MoH is under the General Directorate of Health Research. This committee assesses more general issues like obesity, KOAH etc., instead of certain health technologies and publishes national reports. One of the reports published by this committee was the importance of obesity surgery in the treatment of obesity. In addition to all these three committees, HTA studies also being carried out by a MoH hospital called Ankara Numune Training and Research Hospital (ANHTA). They have been working on hospital-based HTA. CONCLUSIONS: However, high cost drugs meeting end-of-life criteria are not likely to be reimbursed or even considered for reimbursement by HTA agencies in Turkey. However, HTA is still in its infancy in Turkey and compared to other EU countries like Germany, UK etc. there is not an autonomous HTA agency. There are more than one committee, working on different aspects of health technology assessment under the supervision of government.

PHP245 DISEASE BURDEN IN BRAZIL AND HEALTH TECHNOLOGY ASSESSMENT: A RETROSPECTIVE OF TEN YEARS OF SUPPORTING

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BACKGROUND: Defining health technology assessment priorities has been a challenge for the Department of Science and Technology who adopted a prioritization criteria strategy (epidemiologic relevance, services/policy relevance, state of the art, operational feasibility and social demand) for demands from MoH technology. However, evaluation demands do not always correspond to health technology assessment (Hta) and HTA in the UK. In a new regulation the Federal Joint Committee (G-BA) can pass down the analysis and treatment methods with not sufficiently proven benefit, but which show potential as essential treatment alternatives ($337 SGB V). The objective of the present study was to compare the requirements for a successful application with the existing AMNOG (Law on the Economic Situation of the Health Care Market) HTA Company. The applicants must submit valid data on the potential of the method in questions, among other requirements. In one of the first applications in Germany, drug companies have submitted an early application since 2010. This analysis was made for different criteria’s like study and endpoint design, certainty of results of the studies and others. We used our business case as template to extract the key-learning’s and identify the pitfalls in the new process. RESULTS: The new legislation will have a strong impact on the study design and evidence to show the potential of new examination and treatment methods as essential treatment alternatives. A lot of evaluation criteria’s came from the drug assessments but are not applicable to the potential of new examination and treatment methods. CONCLUSIONS: The legislation uses parts of classic HTA assessment on medical drugs to evaluate the potential of new examination and treatment methods. In most cases this is not possible and will decrease the public’s confidence in HTA process.

PHP247 CORRELATION BETWEEN END-OF-LIFE STATUS OF A TREATMENT AND LIKELIHOOD OF A PATIENT ACCESS SCHEME IN THE SETTING OF A NICE REVIEW IN THE UK

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OBJECTIVES: This study aims to assess the existence of a correlation between the applicability of end-of-life treatment criteria and the likelihood of NICE requiring a Patient Access Scheme (PAS) to recommend the treatment for funding. RESULTS: A review of all patient access schemes in existence as of March 2014 for NICE-recommended drugs was conducted to assess how many of those were for medicines which met the end-of-life criteria and whether the supplementary criteria for end-of-life treatments had any bearing on the final NICE recommendation. RESULTS: In total 42 PAS were identified. Of those, end-of-life treatment criteria were met and had bearing on the final NICE guidance in 7 cases (16.7%). End-of-life treatment criteria were considered but were not met in full in the case of 3 NICE reviews (in one of those NICE considered that end-of-life criteria were not met in another review, even though the manufacturer had not applied for those criteria to be considered in the present review). End-of-life treatment criteria were also considered for one additional review where they were a focal point of the manufacturer appeal against the NICE guidance. In one additional case, end-of-life criteria were applied for but had no bearing on the final NICE guidance as the cost-effectiveness threshold was met without the application of special consideration (HRAP and ORCHID). CONCLUSIONS: However, high cost drugs meeting end-of-life criteria (most of which are for oncology indications), as expected, many of them are subject to a PAS in the UK. However, the opposite correlation does not hold true, i.e., the requirement for a PAS in the UK is not restricted to end-of-life treatments.

PHP248 THE COSTS AND EFFECTS OF POST-AUTHORISATION SAFETY STUDIES FOR NEW ACTIVE SUBSTANCES

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OBJECTIVES: At market entry, there usually is uncertainty regarding a new medicine’s benefit-risk profile. Therefore, regulatory authorities may request additional pharmacovigilance (PhV) activities. Regulatory Authorities can request a Post-Authorisation Safety Study (PASS) as a registry, database study, survey, or clinical trial to reduce the uncertainty regarding certain safety risks. We aimed to assess the costs and effects of PASS for centrally approved new active substances (NAS) in Europe in 2007. METHODS: We compared two scenarios for all NAS (n=47): (1) Full regulation: routine PhV activities (spontaneous adverse drug reaction (ADR) reporting) with additional PASSs for some NAS; (2) Limited regulation: only routine PhV activities. For a follow-up period of six years after marketing we assessed the safety-related labeling changes for NAS and identified the source of these changes (PASS, spontaneous ADR reporting or other). Data on labeling changes was extracted from the National Medicines Regulator’s websites. We also assessed the source of adverse safety information in 12 NAS specific companies that were used to estimate the costs of all requested PASSs. RESULTS: For 23 of the 47 NAS, at least one PASS (33 PASS in total) was requested in 2007. After six years, 8.1% of the labeling changes were related to the new NAS. Requested PASS were the source of 4% of all cases of new safety information identified. The total estimated costs of the 33 requested PASS between €50 and €150 million. CONCLUSIONS: For the 2007 cohort of NAS approved in Europe, the total costs of requested PASS were substantial and yet these PASS contributed to the identification of only 4% of all new safety information identified post-marketing for NAS. However, PASS primarily aim to reduce uncertainty regarding safety risks and the (potentially) value of this uncertainty reduction might not fully be captured by assessing health effects alone.