was considered cost-effective. **CONCLUSIONS:** Evidence of a divergence between the WTP and WTA thresholds used by NICE was not found. The slope of the WTA threshold may be slightly steeper than WTP. Based on available evidence, the NICE WTA threshold may be between £21,100 per QALY and £250,000 per QALY.

PHP301

UNDERSTANDING HEALTH TECHNOLOGY ASSESSMENT (HTA) BODIES IN MAJOR ASIA-PACIFIC (APAC) MARKETS: SYSTEMATIC EVALUATION IN 10 APAC COUNTRIES

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OBJECTIVES: Numerous Asia-Pacific countries have created HTA bodies in the last decades. The rapid adoption of resource demanding evidence-based healthcare decision-making has resulted in some HTA bodies conducting independent reviews while others rely on findings from HTA reviews in other countries. The characteristics, attributes, methodologies employed, and referencing practices by HTA bodies vary significantly. The objective of the study was to characterize the HTA bodies, processes and methodologies in major Asia-Pacific markets. **METHODS:** We conducted a systematic review of HTA bodies' documentation of 10 markets in Asia-Pacific region (Australia, China, India, Japan, Malaysia, New Zealand, South Korea, Taiwan, Thailand and Vietnam) and of peer-reviewed publications through PubMed. Over 350 characteristics, attributes assessed and methodologies used by each HTA were assessed and mapped. **RESULTS:** Among the 10 HTA bodies reviewed, Australia is the most well-established and provides most pertinent details in the public domain followed by Japan, South Korea and Thailand. HTAs rely heavily on clinical data obtained from clinical trials, systematic literature reviews and meta-analyses with the exception of Australia and Japan which, in addition, use explicit incremental cost-effectiveness ratio (ICER) thresholds of AUS$50,000/QALY and ¥5,000,000-6,000,000/QALY respectively. Stakeholder participation is not practiced in APAC markets. Most HTAs publish reports of reviews online with varying lag times. Taiwan and Thailand rely on National Health and Care Excellence (NICE) in developing its policies. **CONCLUSIONS:** Some HTA bodies in Asia-Pacific markets are well-established and while numerous are still in the development phases. The main drivers for developing advanced HTA system are a) the high healthcare related economic burden caused by large populations and b) high prevalence of chronic illnesses. Challenges in enhancing the role of HTA bodies in the Asia-Pacific markets include a) limited technical resources and b) lack of real-world evidence. Understanding the factors will help manufacturers plan accordingly.

PHP302

SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS (NMA) IN REIMBURSEMENT SUBMISSION; WHAT NICE SAYS VERSUS WHAT NICE WANTS

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OBJECTIVES: Manufacturers preparing technology appraisal (TA) submissions for the National Institute for Health and Care Excellence (NICE) face a lack of explicit guidance – in NICE's manual guide and from its Evidence Review Groups (ERGs) – on key aspects of conducting a systematic literature review (SLR) and network meta-analysis (NMA) to generate comparative data for their products. We therefore explored whether there are common themes in ERG critiques to suggest NICE uses unwritten standards in assessing such methodology. **METHODS:** All single TA submissions published between December 2015 and June 2016 were identified from NICE's website. Subsequently, one researcher extracted information fromeach submission and related ERG critique on various aspects of the SLR and NMA conducted, with these extracts then being validated by a second researcher. **RESULTS:** Data were extracted from 25 submissions. Heterogeneity due to mixed-population studies (i.e., those in which target patients for the index product were only a subgroup) was noted and was most commonly due to differences in disease severity. Manufacturers' NMA submissions were most often criticised for neither adequately assessing such heterogeneity nor exploring it through subgroup analyses. Also while manufacturers acknowledged that the proportional-hazard assumption is often not met, they had generally taken no steps to control for this in their statistical analysis plans, and this was criticised by the ERGs. Of note, the NICE manual provides no clear guidance on what proportions of target patients there should be in mixed-population studies to make these eligible for inclusion in NMAs, nor on the acceptable level of heterogeneity within such analyses. The NICE manual does provide guidance on dealing with non-proportional hazards but this was not always followed in TA submissions. **CONCLUSIONS:** Recurring ERG criticisms of SLR and NMA methodology in TA submissions suggest that NICE may have unwritten rules in assessing such use of the techniques.

PHP303

FIXED-DOSE COMBINATION DRUGS UNDERGOING AMNOG - LEARNINGS FROM 5 YEARS

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OBJECTIVES: The early benefit assessment (EBA) of pharmaceutical products in Germany has been implemented in Jan 2011. Until 4th of Jan 2016, overall 146 EBA have been finalized. Among them, 20 (13.7%) were on fixed-dose combination pharmaceutical products (FDC). However, only 16 of them were taken into consideration for this analysis because they were newly approved by EMA. The aim of this analysis was to differentiate between the different types of FDC and define key learnings. **METHODS:** We screened the G-BA database regarding finalized EBA of new FDC. We categorized these products by indication and grouped them to six categories which were defined by their combination structure (i.e., generic substance plus generic substance, generic substance plus new substance, and so on). Furthermore, we described the assessments per indication group and discussed the results. **RESULTS:** In the 5 years of EBA, 10% of all finalized assessments were on new FDC. FDC have been marketed only in specific indication areas. They were introduced for the treatment of HIV (25%) and asthma/ COPD (25%), type-2 diabetes mellitus (19%) and HCV (13%) as well as for the treatment of essential hypertension (6%), eye disease (6%) and stomach cancer (6%). Most of these products could be grouped into Category A (new substance plus generic substance) and Category E (already G-BA-assessed substance plus generic substance) (both N= 5). There was no product in Category F (two or more already G-BA-assessed substances). It was evident that the G-BA decision was different among the categories of the FDC. **CONCLUSIONS:** New FDC are not common in the EBA. There is a tendency in which indication FDC products are more common. The type of combination, i.e. combination with or without generic substance, as well as the existence of a specific level of evidence, i.e. direct comparator study vs. bioavailability study only, were key drivers for a successful early benefit process.

PHP304

PERCEPTION SURVEY ON HEALTH TECHNOLOGY ASSESSMENT IN TURKEY: DOES PRACTICE MEET WITH REGULATIONS

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OBJECTIVES: To understand the perspective of stakeholders about HTA related legislation and its actual implementation in Turkish setting and to discuss important issues reported by stakeholders regarding current practice of the HTA process. **METHODS:** One hundred and twenty ISPOR Turkish Chapter members from public, private health sectors and academicians were invited to complete an online survey consisting of 32 items within 12 domains: (1)explicitly stated objectives of HTA (2)positive effect on new technologies (3)collaboration with industry (4)usage of best available data for decisions (5)objectiveness and transparency (6)defined timing and processes (7)involvement of stakeholders (8)early engagement (9)independency of regulatory and reimbursement processes (10)consideration of societal and local issues (11)accountability and equitableness (12)adequacy of resources. All claims were evaluated from regulation and application perspectives using 3 level responses (valid, partially valid or not valid). **RESULTS:** Forty members completed the survey. Responders' mean age was 38.8 years and they were mostly male (62.5%) and from the private sector. Three domains with lowest ratings were the adequacy of resources, consideration of societal and local issues and positive effect on new technologies in application. Three domains with highest ratings were objectiveness and transparency, defined timing and processes, independency of regulatory and reimbursement processes in written regulations. Although private health sector ratings were lower than public and academic ratings, results were generally consistent among different sectors. **CONCLUSIONS:** This survey showed that there are discrepancies between regulations and their implementation in practice in Turkey. Anonymous surveys can be useful to understand issues in a particular health technology assessment system. A workshop including all stakeholders to discuss possible solutions based on the survey results is planned by ISPOR Turkish Chapter.

PHP305

G-BA EARLY ADVICE VS. EMA/HTA PARALLEL ADVICE FROM A GERMAN PERSPECTIVE

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OBJECTIVES: To compare the procedure of a standalone G-BA early advice and G-BA early advice in the context of EMA/HTA parallel advice; to evaluate the value of the feedback received for Germany. **METHODS:** Comparison of two processes: "standalone" G-BA early advice and G-BA advice within EMA/HTA parallel advice and their influence on our process using recent examples. **RESULTS:** Early G-BA advice is an established process that serves to get feedback on company plans for pivotal trial design and the demands for evidence for future benefit assement. EMA/HTA parallel advice with G-BA participation is used increasingly and has the goal of discussing study design questions with all stakeholders involved: although no consolidated feedback is expected, all relevant topics are discussed with all authorities involved. For Germany, there are differences between procedures – while for standalone G-BA advice, a German advice request with questions and positions is prepared, the parallel advice process uses a centrally prepared briefing book. In recent experience, the G-BA has asked for a German advice request and separate F2F meeting to accompany the parallel advice process. This is taking into account aspects that are very specific for Germany (e.g. appropriate comparative therapy according to G-BA´s rules of procedure) that need to be addressed additionally. This has meant that in order to receive feedback that can be used in the German benefit assessment, a part of the German standalone process still applies. **CONCLUSIONS:** Although there is an increase of parallel advice projects and they offer benefits in terms of preparation for the company's national teams, they do not yet replace G-BA early advice. Parallel advice may offer the most impactful route to influence major elements of trial design but it needs to be ensured that country specific aspects are given sufficient coverage for the parallel advice to generate complete, valuable and useful feedback.

PHP306

GLOBAL EVALUATION OF EUROPEAN SUBMISSION TEMPLATE TO INFORM HTA AND PAYER SUBMISSIONS

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OBJECTIVES: Roche supports high-quality, robust and consistent processes to enable HTA evaluations and inform payer submissions. EUnetHTA has developed the HTA Core Model (HTA CM) and European Submission Template (EU ST) which provide a framework for collecting and reporting HTA evidence. Roche has developed an