subsequent decisions by FJC. METHODS: We examined all IQWiG assessments and corresponding FJC decisions up to 01.06.2012 regarding possible disagreements. After reviewing the IQWiG assessments and finding discrepancies, we discussed these findings with a physician and company. The objective is to investigate the challenges within a pharmaceutical company occurring during the preparation of a dossier. METHODS: First, the template of FJC is analyzed to identify the data and skills needed to fulfill the requirements. These requirements are then linked to specialized departments within the company. Finally, governance principles are developed. RESULTS: Data regarding drug and disease, available treatments and guidelines, clinical study program as well as German epidemiology and cost are needed for the dossier. Consequently, profound skills in medicine, evidence-based medicine and biometrics are necessary to support medical writing of the dossier. The departments Medical, Health Economics & Outcomes Research (HEOR), Market Access, Regulatory, Commercial and Legal are crucial for the development of a successful dossier. To finalize the dossier in time, two teams are defined: One operational team with delegates from Medical, HEOR and Regulatory prepares the dossier according to the FJC’s requirements with or without support by an external vendor. Strategic decisions including aspects not confined to the individual product are taken by the cross-functional governance board. Beyond this a close alignment with global and regional Access policies is essential. CONCLUSIONS: The preparation of a dossier requires an area of cooperation at the local level within pharmaceutical companies involving a cross-functional team. Of particular importance are the HEOR and Regulatory departments where essential information and expertise reside, putting these teams in the spotlight.

PHP158
CROSS-FUNCTIONAL CHALLENGES IN THE PREPARATION OF A BENEFIT DOSSIER
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OBJECTIVES: The Act on the Reform of the Market for Medicinal Products (AMNOG) funds, effective since 01.01.2011, implemented an early benefit assessment of drugs after launch in Germany. This assessment is based on a dossier submitted by the manufacturer for which the Federal Joint Committee (FJC) provides a detailed template. The objective is to investigate the challenges within a pharmaceutical company occurring during the preparation of a dossier. METHODS: First, the template of FJC is analyzed to identify the data and skills needed to fulfill the requirements. These requirements are then linked to specialized departments within the company. Finally, governance principles are developed. RESULTS: Data regarding drug and disease, available treatments and guidelines, clinical study program as well as German epidemiology and cost are needed for the dossier. Consequently, profound skills in medicine, evidence-based medicine and biometrics are necessary to support medical writing of the dossier. The departments Medical, Health Economics & Outcomes Research (HEOR), Market Access, Regulatory, Commercial and Legal are crucial for the development of a successful dossier. To finalize the dossier in time, two teams are defined: One operational team with delegates from Medical, HEOR and Regulatory prepares the dossier according to the FJC’s requirements with or without support by an external vendor. Strategic decisions including aspects not confined to the individual product are taken by the cross-functional governance board. Beyond this a close alignment with global and regional Access policies is essential. CONCLUSIONS: The preparation of a dossier requires an area of cooperation at the local level within pharmaceutical companies involving a cross-functional team. Of particular importance are the HEOR and Regulatory departments where essential information and expertise reside, putting these teams in the spotlight.

PHP159
PROPOSED AND ACTUAL BUREAUCRATIC BURDEN OF HTA SUBMISSIONS TO THE INDUSTRY- CASE STUDIES FROM GERMANY AND UK
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OBJECTIVES: To assess the effort it takes for manufacturers to develop HTA submissions in Germany and the UK and to compare it to the estimates proposed by the legislator. METHODS: A review on available sources was conducted to assess the proposed as well as the actual effort it takes to develop and submit a dossier to the German (G-BA/ IQWiG) and the UK (NICE) HTA authorities. The review was supplemented by interviews with experts from pharmaceutical and consulting industry. RESULTS: The time proposed for HTA submission was particular low in Germany were the legislator estimated that a submission to the G-BA/ IQWiG could be done within 2.5-3 days. However, according to the review and expert judgment actual effort of HTA submission in Germany required a minimum of one year for multidisciplinary teams collaborating on generation of evidence following the exact guidance that details the methods, contents, and format of submissions to the German HTA body. Effort in UK is seen as lower due to the more collaborative and interactive nature of the process avoiding unnecessary effort and allowing for a clear focus on the critical questions. However, since the process in Germany is still fairly new, it could be assumed that due to learning curve effort will be lower in subsequent assessments and the process gets more rationalized. CONCLUSIONS: The actual burden exceeds the burden that was estimated particularly in Germany by magnitudes. This study shows that the burden also depends on the organization of the consulting process during dossier development. Whereas the early and structurally interaction in UK was seen as favorable to avoid spending time on aspects that are not relevant for the decision of the HTA body the subsequently revised more than 70% German process where such an action is much less intense requires a more mecha- nistic approach.

PHP160
BENEFITS OF PROBABLISTIC SENSITIVITY ANALYSIS
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OBJECTIVES: Since 2004 the National Institute of Health and Clinical Excellence requires manufacturers to conduct a probabilistic sensitivity analysis for their technology appraisals. The objective of this review is to assess the outcomes of different probabilities of being cost effective and compare this with the actual decision making done by NICE. METHODS: The search term ‘probabilistic sensitiv- ity analysis’ was used on NICE homepage (2012-01-25). The chapters included in the search was assessed and included for further review if a probability of being cost effective in both subgroups of what threshold was mentioned. If several probabilities were provided the number provided by the evidence review group were used rather than those provided by the manufacturer since these numbers are more likely to be used in the decision making. If several scenarios were pre- sented in the same chapter. Finally the ICER assessed as cost effective versus was compared with the actual decision making which could result in 2 outcomes either it was recommended or not recommended. The results were plotted into a graph to illustrate the relationship between PSA outcomes versus final recommendation. The assessments were ranked according to their probabil- ity of being cost effective. A higher probability of being cost effective correlated to more positive decision making and there even is observed a clear threshold whereas technologies with a 40% certainty of being cost effective tend to be recommended (3 outcomes). Whereas those below 70% certainty are not recommended. CONCLUSIONS: Results suggested that ICER estimate was not a robust driver of decision making, NICE applicant should provide an increase attention to PSA on the top of ICER estimate.

PHP161
INTEGRATION OF VALUE OF INFORMATION INTO THE DECISION MAKING PROCESS IN IRELAND
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OBJECTIVES: In Ireland, the National Centre for Pharmacoecomics (NCPE) appraises the cost-effectiveness of technologies in response to requests from the Health Service Executive (HSE). A large number of reimbursement decisions are based upon the appraisal of company Health Technology Assessments (HTAs). HTAs are conducted in accordance with existing HTA Guidelines. These guidelines do not specify the requirement of Expected Value of Perfect Information (EVPI) analysis. METHODS: To examine the application of EVPI analysis as part of the formal HTA process. METHODS: There is no set cost-effectiveness threshold in Ireland; however, technologies with ICERs > €20,000/QALY are less likely to be reimbursed. This threshold was considered here. EVPI estimates at (€20,000/QALY) were determined directly from the PSA results of company economic models. Esti- mates were scaled up to 10 year population EVPI (PEVPI) levels. NCPE recommenda- tions on reimbursement were recorded. RESULTS: The NCPE have estimated PEVPI values since nine company evaluations took place. Seven technologies were developed for newly licensed technologies; eight were pharmaceuticals and one was a diagnostic. Two technologies had ICERs > €120,000 with PEVPI estimates > €20 million; reimbursement was not recommended. Two technologies dominated the relevant comparators and one had an ICER < €10,000/QALY. All PEVPI values were below €1 million. Reimbursement of all three technologies was recommended. The four remaining technologies had ICERs in the range of €21,000/QALY-€30,000/QALY; their PEVPI values ranged from about €1.5 million - €35 million. Reimbursement was not recommended. In two cases (original PEVPI values of €2.4 million and €35 million respectively) the manufacturer subsequently submitted additional data. Reimburse- ment was then recommended. There was no formal reanalysis of PEVPI. CONCLUSIONS: To date, the formal analysis of PEVPI has not affected the decision to accept or reject technologies with ICERS lower and higher than €20,000/QALY respectively.

PHP162
REVIEW OF NICE’S TECHNOLOGY APPRAISAL RECOMMENDATIONS
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OBJECTIVES: To illustrate how decision-making in England and Wales is influ- enced by cost effectiveness and other factors, with particular emphasis on deci- sions for end-of-life treatments. METHODS: An analysis of all technology appraisals published by the National Institute for Health and Clinical Excellence (NICE) from 1st March 2000 to 31st May 2012 was conducted, with recommendations categorised as ‘recommended’, ‘optimised’, ‘not recommended’, ‘only in research’ and ‘non-submission’, by therapeutic area and by technology process (multiple technology appraisal or single technology appraisal). These categories were then mapped against the most plausible cost per QALY estimate and the recommenda- tions were contextualised with the factors used in decision-making. RESULTS: Since 1st March 2000, NICE has published 256 appraisals containing 490 individual recommendations on the use of technologies in England and Wales. The majority (78%) of these recommendations recommended the use of a technology either in line with its licensed indication (‘recommended’) or under specific conditions (‘optimised’). Only in research’ and ‘not recommended’ decisions represented 5% and 14% of all recommendations respectively. Of the 195 recommendations in technology appraisals which considered the use of oncology treatments, 61% were ‘recom- mended’ or ‘optimised’. Since January 2009, 15 end-of-life technologies have been considered of which 9 were recommended because the additional weight that needed to be assigned to the disease made them more cost effective. EFFECTIVE. METHODS: Thirty-one assessments were included for final review. A higher probability of a technology being cost effective correlated to more positive decision making and there even is observed a clear threshold whereas technologies with a 40% certainty of being cost effective tend to be recommended (3 outcomes). Whereas those below 70% certainty are not recommended. CONCLUSIONS: Results suggested that ICER estimate was not a robust driver of decision making, NICE applicant should provide an increase attention to PSA on the top of ICER estimate.