determine any trends and drivers of local decision-making. **RESULTS:** As expected, there was variation across CCGs in funding decisions. However, there was only a limited correlation between funding decisions and CCG priorities or performance. It became evident that there were no strong discernible trends or drivers for local funding decisions on these products. **CONCLUSIONS:** Unlike the national level assessments undertaken by NICE, the drivers of local formulary decisions on new pharmacotherapies are difficult to establish and vary across CCG, making it difficult for pharmaceutical companies to obtain access for their medicines using a "one size fits all" approach. Thus, pharmaceutical companies need to engage more closely with CCGs to better understand their needs (including beyond-the-pill) and demonstrate the 'localised' value of pharmacotherapies.

PHP183

THE GERMAN AMNOG DRUG REIMBURSEMENT PROCESS: FACTORS ASSOCIATED WITH GBA-DECISIONS ABOUT THE ADDITIONAL BENEFIT

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OBJECTIVES: Since the introduction of the AMNOG in January 2011, an early benefit assessment by the German G-BA is required for all new drugs in Germany. Objective of our study was to identify any predictors of G-BA decisions. **METHODS:** All G-BA decisions up to 04/2015 were analyzed; basic characteristics of each drug as well as of each decision were documented. A multivariate ordinal regression analysis, using given additional benefit classification (ranging from 1 for major additional benefit to 5 for no additional benefit) as dependent variable, was conducted. **RESULTS:** 130 completed G-BA assessment procedures were evaluated. Within these, G-BA decisions were as follows: 16.9% of the drugs received considerable additional benefit (for at least one patient subgroup), 23.1% received a minor additional benefit, 10.0% received a non-quantifiable additional benefit, and 50.0% received no additional benefit. Due to the specifics of German value assessment, orphan drugs automatically receive an additional benefit, but 39.1% of the assessed drugs received a non-quantifiable additional benefit (lowest possible assessment). Our multivariate regression analysis showed that the strongest predictors for an above-average benefit ranking were proven advantages in mortality ($p<0.001$) or morbidity ($p=0.001$). Additionally, products for use in malignant ($p=0.013$) or infectious diseases ($p<0.001$) as well as orphan treatments ($p=0.027$) were more likely to reach a better benefit rating. Furthermore, any evidence of a favorable safety profile of a treatment is associated with a better ranking ($p=0.10$). **CONCLUSIONS:** Key factors for positive G-BA decisions seem to be a proven superiority in mortality or morbidity against the standard treatment as defined by the German G-BA. However, this is difficult to prove in specific chronic disease areas, especially if surrogate outcomes are not widely accepted. This may explain why, for example, 80% of the assessed diabetes drugs did not receive any additional benefit in Germany.

PHP184

OVERVIEW OF NUB PROCESS FOR IN-PATIENT DRUGS AND DEVICES IN GERMAN

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OBJECTIVES: In Germany, the reimbursement and pricing of innovative in-patient drugs and devices is managed through the NUB application process. These applications are submitted by the hospital stakeholder and are approved or rejected by the Institute for the Hospital Remuneration System (InEK). The objective of this research was to assess the NUB trends in Germany in 2012-2014. **METHODS:** We developed a database of NUB approvals and rejections based on the Institute for the Hospital Remuneration System's (InEK)'s reports. All information was extracted into Excel format. The following data was extracted: product name, indication, year of submission, number of NUB applications submitted, status score, type of evidence available and lack of evidence for NUB rejection. Additionally, the number of re-applications and re-rejections were also analyzed. **RESULTS:** In 2013 and 2014, a total of 21264 and 25634 NUB applications were submitted for 612 and 613 medical products, respectively. Of these applications in 2013 and 2014, 10% and 16% were approved for NUB (as Status 1) and 82% and 75% were rejected (as Status 2), respectively. In 2014, the median number of hospital applications for NUBs with Status 1 and Status 2 were 37 and 3, demonstrating the importance of hospital participation for seeking NUB approval. Among approved NUBs, 37% of the applications were for drugs and 63% were for devices. Interestingly, the median NUB hospital applications for approved drugs was 192, while for devices, the median was 9 applications. In 2014, 447 NUB applications for products were re-submitted, of which 5 were approved and the remaining were re-rejected. The evidence requirements analysis suggests the need for hospital focused economic data. **CONCLUSIONS:** The NUB process plays a critical role in market access for in-patient drugs and devices. For approval, two key components are: hospital focused economic evidence and provider stakeholder involvement.

PHP185

REIMBURSEMENT OF ORPHAN AND EXPENSIVE DRUGS IN THE NETHERLANDS: EXPLORATION OF ESSENTIAL CRITERIA IN THE DECISION MAKING PROCESS

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OBJECTIVES: The aim of this study is to (i) review the methodological quality of pharmacoeconomic evaluations of orphan and expensive drugs that applied for reimbursement in The Netherlands, and (ii) explore essential criteria in the reimbursement recommendations made by The Dutch National Healthcare Institute (ZINL). **METHODS:** Data were extracted from pharmacoeconomic reports published by ZINL between 1 January 2006 and 31 December 2013 using a data extraction form. Compliance to pharmacoeconomic guidelines was determined by evaluating deviations in the pharmacoeconomic reports from the list of provided items in the guidelines. Multiple variables (i.e. drug safety, efficacy, therapeutic value, and cost-effectiveness) were investigated regarding their influence on the reimbursement recommendation by performing the Pearson's Chi-squared test, Kolmogorov-Smirnov test, and Wilcoxon rank sum test. **RESULTS:** In total, 53 pharmacoeconomic evaluations were included in this study. Of these, 16 concerned orphan drugs, while 37 evaluated high cost- drugs. Of the 53 pharmaceutical compounds evaluated in this study, 39 (73.6%) received a positive reimbursement advice, 11 (20.8%) received a negative reimbursement advice, and 3 drugs were not assessed for reimbursement through either the outpatient reimbursement system nor the intramural high cost reimbursement system (5.7%). In total, 277 deviations from the pharmacoeconomic guidelines were observed, but no single item was found to have a statistically significant effect on the reimbursement recommendation. In contrast to drug safety and cost-effectiveness outcomes, both drug efficacy and therapeutic value showed to have statistically significant impact on the reimbursement decision. **CONCLUSIONS:** In The Netherlands, drug efficacy and therapeutic value can be considered as essential criteria in the reimbursement decision of orphan and expensive pharmaceuticals, resulting in a reimbursement system being centered on clinical value. Even though cost-effectiveness does not have a significant impact on the decision, compliance in the reimbursement dossiers by manufacturers to the Dutch Guidelines for Pharmacoeconomic research can be further improved.

PHP186

PERFORMANCE OF DRG-BASED REIMBURSEMENT POLICY IN NATIONAL HEALTH INSURANCE : EIGHT YEARS' EXPERIENCES

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OBJECTIVES: The diagnosis-related group (DRG) based reimbursement system has been voluntarily applied to inpatients with seven diseases in the Korean national health insurance since 2002, and was mandatory for all health-care institutions from July 1, 2013. The main purpose of this study was to evaluate the performance of DRG-based reimbursement in health care expenditure and to propose alternative policies. **METHODS:** A non-equivalent control group pretest-posttest design with a difference-in-difference approach was adopted to compare changes in medical service utilization and physician's behavior between DRG-based reimbursement(experimental group) and fee-for-service reimbursement(control group). Seven diseases to which DRG-based reimbursement was applied included tonsillectomy, cataract surgery, appendectomy, herniotomy, hemorrhoidectomy, hysterectomy, and Caesarean section. The panel data were produced from year 2004~2011 medical claims database of the National Health Insurance, which covered a total of 1,119,028 cases per year. **RESULTS:** From 2004 to 2011, surgical operations in institution reimbursed by DRG have been significantly increased more than those in institutions reimbursed by fee-for-service. The results showed that the DRG-based payment has reduced the length of stay in seven diseases, while it has changed physician's behavior to charge DRG-code upward and shift medical tests and expensive antibiotics from inpatients to outpatients because DRG was applied to inpatient only. The DRG-based payment in seven diseases has consistently increased medical expenditure as well as medication expenses more than fee-for-service, partly due to no global budget in the Korean national health insurance. **CONCLUSIONS:** Challenges and future issues to expand the DRG-based reimbursement system to all diseases for inpatients should be considered such as monitoring service quality, strategic plans to control physicians' behavior, limiting the number of DRG classifications, and the introduction of global budgeting.

PHP187

IMPACT OF ESSENTIAL HEALTH BENEFIT BENCHMARK PLANS ON US MARKET ACCESS

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OBJECTIVES: Beginning in 2014, the Affordable Care Act requires new health plans to cover essential health benefits (EHB), including pharmaceutical products, according to the state level benchmark plans. The objectives of this analysis were to understand state level variations in design of plans, access to drugs and likely impact on patient choice and health outcomes. **METHODS:** Benchmark plans for the top five states (i.e., FL, IL, NY, TX and CA), covering ~116 million lives, were obtained from the CMS. For each plan, the categories, classes and number of covered drugs was collected and pooled into one database. Analysis was conducted at the entire population level, state-level and for top classes of drugs. The comments from patient groups were reviewed to understand the impact of EHB on patient choice and health outcomes. **RESULTS:** Benchmark plans for the top five states provide coverage of 4215 drugs belonging to 158 classes as defined by USP. While four states (FL, IL, NY and TX) had a similar number of covered drugs (median of 892 drugs), CA had a significantly lower number of covered drugs, amounting to 28% less than the other four states. On average, 10% of the drugs were in the class called "No USP Class", highlighting the limitation of CMS designated USP classification system for the new plans. In CA, FL, IL, NY and TX there were 18, 7, 8, 11 and 8 classes, respectively, for which only 1 was covered. In CA, top 8 classes were identified for which patients had a 75% lower choice than other states, and these included indications such as Anti-Diabetics and Pain medications. **CONCLUSIONS:** Review of new benchmark plans shows some states can have a significantly lower patient choice of therapies. There is a need for new policy measures to ensure that all patients have equal access to new treatments.

PHP188

A SIMULATION ANALYSIS USING THE ORANGE PRICE REFERENCE TOOL

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OBJECTIVES: International Reference Pricing (IRP) is a key cost-containment tool for health care payers across the world. IRP may apply either fixed or flexible

rules to calculate the price of branded drugs. Typically there is no negotiation between manufacturers and the IPR body. In the context of the German AMNOG price negotiations and the role of Germany as a key reference country, there is dearth of evidence on the international impact of the AMNOG law. Our objective was to evaluate the potential impact. **METHODS:** An IRP tool (Orange) was used to simulate scenarios of price agreements for a new branded drug between the German Head Association of the Statutory Health Insurance Companies and the manufacturer. The impact of the price agreement on other countries was evaluated based on the existing IRP rules as defined in the Orange tool. All prices were initially set at 100 euro to limit the impact to Germany only. **RESULTS:** A 50% price drop in Germany, for example, would lead to a range of reductions across the world. The largest impact in Europe would be in France, Romania, Russia, Slovenia and Luxembourg (50% decrease) followed by Norway, Greece (17%) and the Netherlands (13%). Switzerland, Ireland, Denmark and Austria would be only marginally impacted. In contrast, with a price increase in Germany of 25% a limited impact in other countries was observed. Such an increase would lead to 6% price rise in the Netherlands, 4% in Switzerland, 3% in Ireland and Denmark, and a 1% increase in Austria. **CONCLUSIONS:** Price negotiations in Germany could potentially impact the price of new branded therapies in numerous other countries. Ongoing downward pressure on pharmaceutical prices could ultimately have a negative impact on innovation and drug development in Europe.

PHP189

ULTRA ORPHAN AND CANCER DRUG PRICING TRENDS IN THE US AND THE UK

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OBJECTIVES: Both ultra orphan and cancer drugs are premium priced therapies with high annual per patient costs. The local legislation and reimbursement mechanisms have had significant impact on pricing trends for these therapies. The objectives of this analysis were to compare the price differential for ultra orphan and cancer drugs in the US and the UK, and understand the impact of local reimbursement mechanisms. **METHODS:** A set of 22 drugs (10 ultra orphan and 12 cancer drugs) was selected based on their availability in the US and the UK. The 2014 AWP, WAC and net prices were obtained for all 22 drugs. All UK prices were converted to USD. Primary discussions with ex-payer and policy experts were conducted to understand the basis and implication of the price differentials. **RESULTS:** For ten selected ultra orphan drugs, the median WAC price premium for the US compared to the UK net price was 10%. For 12 selected cancer drugs the median WAC price premium for the US compared to the UK net price was 106% (based on AWP the premiums were 29% and 149%, respectively). Eight out of 10 ultra orphan and 12 out of 12 cancer drugs were higher priced in the US compared to the UK. Primary discussions with experts suggest the role of legislation for coverage of cancer drugs in the US and special coverage of rare disease products in the UK and reimbursement mechanisms (use of cost effectiveness driven HTAs in the UK and the use of co-pay in the US) as primary drivers of high price differential for cancer drugs versus ultra orphan therapies. **CONCLUSIONS:** The local reimbursement mechanisms are major drivers of price differential for ultra orphan and cancer drugs in the US and the UK.

PHP190

DISCOUNT DISTRIBUTION ANALYSIS OF ORIGINAL MEDICINES WHICH HAS NO GENERICS IN TURKEY

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OBJECTIVES: Pharmaceutical industry continues to grow and drug prices are a burden for countries. Reference price system is assumed that such a practice concerning medicines will lead to a decrease in medicine expenditures as medicine prices decrease. The objectives of this analysis to determine the distribution of discount of original medicines which has no generics from the reimbursement agency perspective in Turkey. **METHODS:** In the analysis,"Detailed Price List" data published on the website of the Ministry of Health's Turkish Medicines and Medical Devices Agency(TMMDA) and "Annex 4-A Funded Medicines List" data published by Social Security Institution(SSI) were used. The lists were merged using the Excel software and generic medicine including genericized original medicines with different pricing and payment conditions compared to original medicines with no generics and other specific medicines such as blood products,enteral nutrition products, etc. and specific conditions such as medicines with no reimbursement were excluded. The analysis was made with a total of 568 original medicines with no generic. Ex-factory prices were used in the analysis. The reference prices of all original medicines (100%)are calculated by multiplying their actual reference price values with the periodic Euro value in the price list used in Turkey. **RESULTS:** A comparison between ex-factory prices in TL and actual reference prices in TL revealed that 42.6% of the medicines had the same price,while 57.4% had a different price.The distribution of discount rates applied by SSI for 370 original medicines with a 41% discount rate and 99 original medicines with a 32.5% discount rate were found. **CONCLUSIONS:** In this analysis the mandatory discount rate for original drugs of 41% discount is mostly implemented by SSI. In rare cases, higher or lower discount rate can be applied. This is compatible with the implementation of the original drug reimbursement policy rules. However, further analysis should be done to obtaining more detailed information.

PHP191

IMPACT OF ASSESSMENTS OF NEW MEDICINES BY THE SMC IN ENGLAND

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OBJECTIVES: The Scottish Medicines Consortium (SMC), unlike the National Institute for Health and Care Excellence in England, assesses all new medicines. It is often assumed that the assessment by the SMC influences subsequent local recommendations on the funding and use of medicines in England. This research tests that hypothesis. **METHODS:** Research was based on 86 medicines assessed by the SMC in 2012 and 2013, of which 56 were not reviewed by NICE. A sample of five local assessment groups in England was identified. From these we found a total of 53 recommendations relating to medicines not reviewed by NICE, of which 27 were published subsequent to the SMC assessment. **RESULTS:** Only around half (51%) of local assessments in England were published subsequent to SMC assessments, so could potentially have been influenced. Of these recommendations two-thirds (18) were consistent with the SMC verdict, and one third (9) differed. Detailed analysis revealed additional factors. Several of the medicines in the sample were recommended by NICE on the basis of evidence summaries or in clinical guidelines. This advice, although not mandatory, appears from our sample to have been followed. Also some medicines not recommended by SMC were subject to specialised commissioning, the responsibility of NHS England rather than local commissioners. **CONCLUSIONS:** There is some consistency between assessments of new medicines in Scotland and England (as might be expected given that the evidence and decision criteria are broadly similar) but there are also significant differences. It appears English advisory bodies make their decisions independently of SMC recommendations, and often earlier. Other differences, such as NICE evidence summaries and Specialised Commissioning in England, further reduce the influence of Scottish decisions.

PHP192

REGULATIONS OF THE GERMAN DRUG MARKET

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OBJECTIVES: The framework specifications on pharmaceuticals (Rahmenvorgaben Arzneimittel) by the National Association of Statutory Health Insurance-Accredited Physicians (KBV) and the Statutory Health Insurance Scheme (GKV-Spitzenverband) are annually redefined. These specifications (Rahmenvorgaben) are binding for the 17 subnational drug agreements (Arzneimittelvereinbarungen) and target agreements (Zielvereinbarungen). They include quotas for lead compounds and prescription quotas. Individual subnational districts (KV Gebiete) set local drug specifications and quotas. These guide the prescription behavior. The objective of the analysis is to identify differences between the subnational regions regarding target agreements and resulting impacts. The analysis focuses also on the shift from innovative biologics to biosimilar products. **METHODS:** The 17 subnational drug target agreements (Zielvereinbarungen) are analyzed regarding their differences/specialities and their regulatory effect on the prescription of pharmaceutical classes e.g. anti-diabetic, anti-hypertensives, and the biosimilar proportion. Additionally the rapid prescription information of the SHI (GKV-Arzneimittel-Schnellinformation =GAmSi-data) and local regulation instruments are reviewed. **RESULTS:** The 17 target agreements (Zielvereinbarungen) for the 15 defined classes of pharmaceuticals result in different quota fulfillment. An example is erythropoetin with a quantitative quota range from 20% to 63%. The qualitative regulatory actions regarding the switch of biologics (Erythropoetin, Somatropin, Filgrastim, TNF alpha-blocker) to biosimilars vary from no regulation to recommendation or even priority prescription. The additional defined subnational target agreements (Zielvereinbarungen) include targets on diabetes test strips, biosimilar quotas, individual substances or product-classes and can be individually adapted for the different physician specialties. **CONCLUSIONS:** In addition to the federal regulation system the German pharmaceutical market is fragmented in 17 subnational areas leading to different treatment behavior depending on the relevant subnational target agreements and the defined quotas. This analysis shows the wide variety of the subnational target agreements for different drug classes. They are not uniform and on a qualitative basis they even can exceed the determined federal targets.

PHP193

A SYSTEMATIC COMPARISION OF IQWIG RECOMMENDATIONS AND G-BA DECISIONS IN THE AMNOG PROCESS IN GERMANY

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OBJECTIVES: Since the introduction of AMNOG more than 100 IQWiG recommendations and G-BA decisions on the early benefit assessment have been published. In various assessments, the IQWiG recommendation and the related G-BA decision differ in terms of argumentation and result. In this study, these differences were systematically analyzed in order to draw conclusions for further proceedings. **METHODS:** Data of all published IQWiG recommendations and G-BA decisions were standardized and transferred into the Prismaccess database. In a systematic analysis, major differences between the recommendations and decisions were quantitatively assessed. All documents of the identified decisions where differences were observed were then compared qualitatively. **RESULTS:** In several aspects, major differences were found between IQWiG recommendations and G-BA decisions in approximately 25% of all cases. On the subgroup level, it was observed in at least n=10 cases that the G-BA tends to use a broader definition of subgroups in its decisions than used in the IQWiG dossiers, (e.g. Telaprevir). In terms of the extent of the additional benefit, 17 differences between IQWiG and G-BA decisions were registered, while mostly G-BA tend to evaluate better than IQWiG. In the probability of the additional benefit also some differences were observed. This can be explained by the opportunity to provide additional/new evidence during the oral hearing, which may influence the decision positively. Some proceedings were identified that took another way, as intended by the legislature: for example with Cobicistat, an incomplete paperwork was handed in, to achieve at least the price of the ACT. Still accepted by the G-BA, it is obvious that this should not be the normal case. **CONCLUSIONS:** In an early stage, G-BA consultations might be helpful clarifying subgroups-requirements. In the process, the oral hearing was identified as important instrument to supplement the required data and to correct uncertain issues from the dossier.