Rejection was more common for manufacturer’s comments on outcomes (6/8, 75%) and comparators (8/13, 61.5%). Rate of final recommendation by NICE was higher for those M’s where all (29/40, 74%) or certain changes (14/20, 74%) requested by the manufacturer were implemented in the final scope than for those where NICE rejected all manufacturer requests (7/11, 64%), and similar to overall recommendation and decision drivers (8/13, 61.5%). The data also indicate that the manufacturer’s suggestions are often incorporated in the final scope. NICE not implementing manufacturer’s suggestions to the final scope does not decrease the likelihood of being funded.

PHP159
AN EXAMINATION OF THE REGULATORY AND REIMBURSEMENT PROCESSES FOR BIOBETTERS AND COMPARISON WITH BIOSIMILARS
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OBJECTIVES: Biosimilars and biobetters are subsequent versions of licensed innova-
tor biotherapeutics. Whereas biosimilars are comparable to the originator product in terms of quality, safety and efficacy, biobetters incorporate intentional modifi-
cations to the originator molecule profile with the aim of producing a superior product. This distinction between biosimilars and biobetters has important impli-
cations from a regulatory perspective, with biosimilars following class-specific guidance whereas biobetters are considered innovator drugs. This study sought to examine and compare the regulatory and reimbursement approaches to the appraisal of biobetters and biosimilars. METHODS: Biobetters and biosimilars of the same product class were identified, and qualitative analyses of the recommen-
dations, methods, and regulatory guidance considered. Specific decision drivers and case studies were taken using available regulatory and HTA reimbursement decision documentation from six European countries. RESULTS: Findings for filgrastim are presented as an example; 7 biosimilars, and the pegylated filgrastims (pegfilgrastim and lipfil-
grastim) considered biobetters, were identified. Biosimilars filgrastims were granted European marketing authorisation based on demonstration of clinical comparabil-
ity in one indication and extrapolation of the scope to all 5 approved indications. Pegfilgrastim demonstrated clinical non-inferiority to filgrastim in one indication and was approved solely for this indication, the subsequently developed ligeplaggrastim was approved for the same indication but used pegfilgrastim as a reference product. Within this context, the biosimilar filgrastims, economic evidence in the form of cost-minimisation analyses was considered in HTA recom-
 mendations of both pegylated filgrastims. This differs from the approach for certain other biobetters that have demonstrated clinical superiority and cost-effectiveness versus their originator. CONCLUSIONS: Biosimilars and biobetters are subject to distinct regulatory processes and the decision driving factors for reimbursement also differ among currently licensed biosimilars. With the development of these products gaining momentum, it will be interesting to observe how the appraisal processes evolve to address the scope and variety of emerging biobetters.

PHP160
TIME LIMITS RESTRICTION IN GERMANY
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OBJECTIVES: In Germany, with the introduction of the Pharmaceutical Market Restructuring Act (AMNOG) in January 2010, pricing and reimbursement deci-
sions for biologics have been driven by the early benefit assessment (EBA). G-BA can decide to set or not a time limitation to the decision. The objectives of this study were, first, to review the number of time-limited decisions over time and second, to evaluate if some of these decisions were not maintained. METHODS: From the introduction of AMNOG Law to June 1st 2014, were reviewed. Exempted and/or cancelled procedures were excluded. RESULTS: As of June 1st 2014, 76 EBAs were concluded and time limits, from 1 to 5 years, were imposed on 28% (21/76) of these decisions. Short-term restrictions (≤2 years) accounted for 52% (11/21) of the time-
limited decisions and long-term (≥2 years) for 48% (10/21). Time-limited decisions concerned largely oncology drugs (62%; 13/21), followed by endocrine/metabolic drugs (19%; 4/21) and neurology drugs (10%; 2/21). The number of time limited deci-
sions increased over the studied period, from none (0/2) of the decisions in 2011 to none (0/2) of the decisions in 2014. CONCLUSIONS: Time-limited decisions are more frequent for ultra-orphan products. Pegfilgrastim demonstrated non-inferiority to filgrastim in one indication and was approved solely for this indication, the subsequently developed ligeplaggrastim was approved for the same indication but used pegfilgrastim as a reference product.

PHP162
GLOBAL HTA ASSESSMENTS OF ULTRA-ORPHAN PRODUCTS: A CASE STUDY OF ECULIZUMAB (SOLIRIS) AND IDURONATE-2-SULFATASE (ELAPRASE)
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OBJECTIVES: As of June 1st 2014, 76 EBAs were concluded and time limits, from 1 to 5 years, were imposed on 28% (21/76) of these decisions. Short-term restrictions (≤2 years) accounted for 52% (11/21) of the time-limited decisions and long-term (≥2 years) for 48% (10/21). Time-limited decisions concerned largely oncology drugs (62%; 13/21), followed by endocrine/metabolic drugs (19%; 4/21) and neurology drugs (10%; 2/21). The number of time limited decisions increased over the studied period, from none (0/2) of the decisions in 2011 to none (0/2) of the decisions in 2014. CONCLUSIONS: Time-limited decisions are more frequent for ultra-orphan products. Pegfilgrastim demonstrated non-inferiority to filgrastim in one indication and was approved solely for this indication, the subsequently developed ligeplaggrastim was approved for the same indication but used pegfilgrastim as a reference product.

PHP163
EVIDENCE-BASED MARKET ACCESS VALUE RESOURCE: NAVIGATING THE HURDLES FOR A BIOTICOGNING A LICENSE IN A SECOND INDICATION IN KEY EUROPEAN COUNTRIES
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OBJECTIVE: Market access for an innovative technology, such as a biologic obtaining a license in a second indication, can be complex and time consuming. Reimbursement is critical to rapid adoption of and optimal patient access to a new technology. This study aimed to determine the best approach for communicating value and providing field-based staff with value resources to facilitate dialogue with stakeholders in various scenarios. METHODS: We conducted desktop research of published literature, health technology assessment reports, clinical trials data, and websites or other resources critical to decision making to develop a reimbursement decision making in order to prepare a communication resource. We conducted a country-affiliate workshop and qualitative one-on-one interviews with key opinion leaders in each country to understand the most appropriate means of communicating value to external decision makers. RESULTS: The process and restrictions for biologics may be stricter than for other medications because of perceived high cost. There are multiple appropriate access and reimbursement options for various patient care models, all with different costs and value drivers. It is critical to understand the needs of external decision makers and provide field-based staff with a consistent yet customizable means of communicating the value of new technologies. All evidence and insights were synthesized into an evidence-based market access value resource for key stakeholders.
engagement. CONCLUSIONS: The evidence-based market access value resource approach provides a clear, concise, and globally integrated value story that will assist in market access and form the basis of consistent communication regarding value at the national, regional, and local level across external stakeholders (e.g., payer decision makers, physicians, patient advocates). Access for a biologics will be considerably longer, away, decisions and adoption of a new technology are diverse and dispersed across and within countries, with varying levels of required evidence.

PHP164 MEDICARE PROVIDER UTILIZATION AND PAYMENT DATA: THE BOOK TO BILL GAP
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The United States spends all other top 10 developed nations, with no zero in life expectancy. Increasing transparency in health care spending could help address this cost to outcomes gap. CMS’ recent release of Medicare Part B Utilization and Payment data, covering 880,000 providers and $77 billion in Medicare pay-
makes, is a significant step toward this goal. OBJECTIVES: Understand differences in billed versus paid amounts for provider and procedure types reported in Medicare data. METHODS: Descriptive and inferential statistics were run on provider special-
cieties representing greater than 2% of claims to describe the differences between maximum allowed Medicare payment amount, amount billed by providers, and the amount reimbursed. Geographical variation was also explored. RESULTS: Amount billed is at least double the amount paid and double the maximum allow-
able amount for all the specialties explored, amount billed versus paid varied significantly by specialty, with some specialties billing as much as six times what they are paid. Largest discrepancies were in anesthesiology (on average billing $385, versus $328 allowed and $110 paid). Other specialties with significant disparity include cardiology, diagnostic radiology, emergency medicine, ophthalmology, and orthopedic surgery, within certain specialties, specific procedures showed ranges of billed versus paid. Across all specialties, the average amount billed was 90% of maximum allowable, and each state is represented in line with census data for the Medicare population; state differences in amount paid versus billed and allowed is not significant. CONCLUSIONS: In analyzing payer and provider data to increase transparency there is heterogeneity between what is paid versus billed across specialty. There is an opportunity to focus attention on narrowing this gap for high-value procedures through evidence and education of patients, payers, and providers to ensure patients receive appropriate treatment, and providers are appropriately reimbursed.

PHP165 CLAIMS REIMBURSEMENT ANALYSIS OF THE NATIONAL HEALTH INSURANCE SCHEME IN GHANA
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OBJECTIVES: To assess the value and service quality of the National Health Insurance Scheme (NHIS) benefits. METHODS: A review method was employed to analysis medical claims for the 2011 to 2013 period. The medical claims were retrieved from the database of the Ashiedu Keteke District NHIS Office. The incurred claims ratio, promptness of claims settlement, and claims rejection ratio indicators of benefit value and service quality were analyzed. RESULTS: A total of 421,574 medical claims with a cost of GH¢75.3 million (US$40.5 million) were analyzed. These claims came from thirteen accredited health care providers-three public health facilities, four private clinics and six community pharmacies. The incurred claims ratio were settled significantly from 4.3 to 7.2 over the period, 2011-2013. The proportion of claims settled beyond 90 days increased consistently from 26% to 90% over the same period. Although, the proportion of claims rejected increased from 0.9% to 3.6% over the period under review, overall, it was low. The reasons for rejection included provision of benefits to ineligible subscribers and breach of sub-
mits to certain expense category. CONCLUSIONS: There is increased awareness and utilization of health services; however, there are considerable delays in claims settlements. It would be necessary for management of the NHIS to settle claims in time to ensure that health care providers are financially resourced to render service to subscribers.

PHP166 NATIONAL HEALTH INSURANCE FUND DRUG EXPENDITURE IN BULGARIA, 2007-2012: REFERENCE BASED PRICING ALONE OR IN COMBINATION WITH OTHER APPROACHES TO PRICING
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OBJECTIVES: Our team wanted to compare the economic effect of restricted market access and reference based pricing (RBP) vs. RBP alone in two consecutive periods, 2007—2009 and 2010—2012. METHODS: We used the officially published cash drug expenditure costs of the National Health Insurance Fund (NHIF) for each of the years from 2007 to 2012. Then we compared the data about the expenditure for drugs, as well as the data about drug budget control. RESULTS: While restricted market access and RBP has been applied between 2007 and 2009, the NHIF drug expenditure increased with 1% (from EUR 144 mln to EUR 166 mln). For that period, the drug expenditure was generally 100% within the budget. From 2010 to 2012, while only RBP has been applied, the drug expenditure increased with 62% (from EUR 187 to EUR 303 mln). For the period, the drug expenditure exceeded the NHIF budget with 5% in 2010, 34% in 2011, 20% in 2012. CONCLUSIONS: RBP alone cannot control the drug expenditure in a long-term. Additional measures are needed together with RBP Performance based pricing, differential pricing, comparative pricing, profit control and price-

volume agreements may be considered as additional to RBP measures for pricing and budget control.

PHP167 EVALUATION OF SOCIAL WELFARE PART OF HUNGARIAN DRUG PROVISION (2011-2012)
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OBJECTIVES: The part of Hungarian drug provision system, which is available on social welfare list, changed several times and in different extents in recent years. The introduction of drug budget in 2006 and simultaneously the abolition of social welfare drug list implied the most significant change. The chief aim of our analysis was to give a comprehensive overview about the main trends on this field examining the range of available products on social welfare list based on different aspects, also concerning the trends of demand, product structure, expenditures and reimbursement. METHODS: Determination of key points of RBP in Hungary. The investigation was performed in the Hungarian Health Fund and published number of patients involved in this reim-
bursement category were considered as the key sources and indicators of our analysis. RESULTS: The decrease of reimbursement categories within reimbursement out-
flow increased. Demand moved to more expensive products, while patients were able to access to more innovative active ingredients in higher level reimbursement categories. Strong correlation can be observed between changes of acts and breaks in turnover trends. CONCLUSIONS: Results of the analysis may support objective judgement of the present social welfare provision system, as well as may contain considerable consequences regarding to potential ways of future structural changes, considering both interests of entitled patients (right to access innovative therapies) and the Health Fund (increase savings, improve efficiency). CONCLUSIONS based on real world (patient level) data may result more complex investigation opportunities of this patient segment and reimbursement category.

PHP168 ANALYSIS OF NEW MODEL OF THERAPEUTIC POSITIONING REPORTS AS A P&R DECISION-MAKING TOOL IN SPAIN
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OBJECTIVES: This study aims to determine if the recently proposed model for thera-
peutic positioning reports (IPRs) in Spain is actually being used as a supportive tool for pharmaceutical pricing and reimbursement (P&R) decisions whilst deliver-
ing a tool for transparency and market access. METHODS: Primary analysis was conducted with regional payers on the proposed model of IPRs, which contain a comparative evaluation on effectiveness and safety, as well as information on market access (such as how to implement and what is the potential impact on drug expenditure). We used the officially published data. RESULTS: The publication of IPRs has brought quicker uptake and greater homogenization to the market access of certain medicines. Notably, according to primary research, protease inhibitors were made available in all autonomous com-
munities (CCAs) two months after the IPR publication. However, the deadline of 3 months for the publication of IPRs is generally not being met. As delineated in the methodology, IPRs are starting to be used as a basis for P&R decision-making in Spain and play an important role in the identification of the most suitable target patient population. IPRs are also delivering on promises of generating consensus among the Spanish CCAAs. IPRs are being used to support the Inter-ministerial Commission of Medicine Prices and the Directorate General of Pharmacy and Basic Services role in P&R. If accepted by the majority of the CCAAs, IPRs will also serve as a tool to evaluate and limit discrepancies in innovative medicines access throughout Spain. There is a lack of consensus of whether an IPR should include an economic evaluation from the start. Contrary to manufacturers, regional payers generally believe its inclusion would help with the selection of more cost-effective medicines whilst aiding with the adoption of IPRs in general.

HEALTH CARE USE & POLICY STUDIES – Health Care Research & Education
PHP169 ESTIMATION OF REFERRAL UTILIZATION RATE: LINKING HOUSEHOLDS TO HEALTH CARE SYSTEM; KENYAN RURAL SETTING EXPERIENCE
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OBJECTIVES: Referral utilization is defined as the number of patients referred and seen by physicians. The objective was to establish referral utilization rate among sick people and the importance of referral systems to community health workers. Sick people were identified with referral and counter referral slips to take to the hospital. METHODS: This was a quasi-experimental study carried out in two sub-locations of Kisumu, Kenya. Under this condition, community health workers were trained on community based referral and counter referral model and issued with referral tools. Each was assigned 25 households, instructed to regularly issue with referral tools. The study showed that 82% (263/322) of the patients arrived in hospital with referral slip the same day.