companies. METHODS: We identified branded antidepressant and antipsychotic launches between 2005 and 2010. Market authorization dates and P&R dates were sourced from national databases and launch dates were determined using IMS MIDAS data. The average time between market authorisation, P&R and launch was then calculated for fifteen European countries. RESULTS: In most countries the identified products were not launched until P&R was secured, making it a significant barrier to patient access. The average time taken to achieve P&R was approximately 310 days, with significant variation between countries. This delay was frequently longer than the average P&R delay seen across all therapy areas. On average only the UK, Germany and Denmark achieved P&R within Transparency Directive guidelines. Significant delays were seen in Portugal and France, with their average 550 and 610 days respectively to gain P&R. CONCLUSIONS: In addition to known development challenges for CNS products, manufacturers experience greater delays in securing P&R in Europe, denying patients timely access to these drugs. In order to improve the intranational transparency of the decision-making process, implementation of the current Transparency Directive is recommended. If proposed changes are implemented to reduce the delay to 120 days, even fewer will be compliant. P&R is an additional hurdle to access that particularly impacts CNS drugs, and stronger efforts to reduce these delays are needed.

DU4
INAPPROPRIATE USE OF DRUGS INFLUENCES HEALTH BUDGET OF POPULATION
Sabo A, Tomic Z, Calasan J, Miljevsic B, Vukmirsov S
Faculty of Medicine, University of Novi Sad, Novi Sad, Serbia and Montenegro
OBJECTIVES: Recently, there is growing evidence of inappropriate variation in use of certain medicines. In Serbia the consumption of pentoxyfiline, dihydroergotoxi- nine, nercigol, deproteinized calf blood extract (DCBE) and cinnarizine, drugs with uncertain clinical benefit (UCB drugs), with clinical trials with little evidence suggesting their clinical benefit, is unusually high. The aim of this study was to analyze the consumption of UCB drugs in second largest city in Serbia – Novi Sad, in 1984 and 2008, to compare with those in entire Serbia, Denmark and Norway, and to examine the potential impact on population budget. METHODS: The study included data on consumption of these medicines in 1984 and 2008, in Novi Sad. Data were obtained from all state-owned and private pharmacies on the territory of Novi Sad. The number of (DDD/1000 inh/day) was calculated using ATC/DDD methodology. RESULTS: Total consumption of analyzed drugs with uncertain clinical benefit in Novi Sad has surprisingly increased in 2008 (12,566/DDD/TI) in comparison to 1984 (7,377/DDD/TI). Also, their total consumption in entire Serbia in 2008, was higher than in Novi Sad (16,723/DDD/TI) and even several dozens medicine have even significantly higher than in Denmark and Norway (0.206/DDD/TI). The money which population spent for UCB drugs yearly was more than 90 Mill EU in Serbia. Although different administrative and educational approaches were applied in Serbia, their use not only did not decrease, but has significantly increased throughout years. CONCLUSIONS: These results suggest the need for putting greater efforts into ed- ucation of general population who buys the UCB drugs in high amounts on their own accord. The work is part of SerbianSP No41012.

PODIUM SESSION III: DRIVERS OF REIMBURSEMENT TECHNOLOGY

RE1
FACTORS INFLUENCING DRUG REIMBURSEMENT DECISION IN SCOTLAND
Charokopou M, Heeg B, Majer IM
Faculty of Medicine, University of Hamburg, Hamburg, Germany, University of Copenhagen, Copenhagen, Denmark, Erasmus University, Rotterdam, The Netherlands
OBJECTIVES: A reimbursement prediction model was previously developed based on a dataset of submissions to the Scottish Medicines Consortium (SMC) between 2008 and 2010. The aim was to update and re-analyze the dataset, and to test internality by extending the validity of the prediction model on submissions from 2011 and 2012. METHODS: A database of submissions between January 2005 and March 2012 was created. Data of 405 applications were collected, including information on the reimbursement decision (yes/no), clinical data and indicators of the health economic model quality supporting the submission. The impact of these variables was estimated with univariate and multivariate logistic regression models. The multivariate model was identified by a backward selection procedure. Internal validity was assessed by the area under the receiver operating characteristic (ROC) curve. External validity was conducted and by judging a classification test to predict the SMC decision based on 2011-2012 data. RESULTS: Out of 405 applications 226 received positive recommendation (56%) and 131 (38%) of them were reimbursed with restriction, e.g. limited patient population or restricted time period. Based on univariate analysis the variables found to have a significant effect on the reim- bursement: poor pharmacoeconomic analysis design (OR = 0.03), high ICER (OR=0.16) and unclear/ inferior efficacy outcomes (OR=0.25). The final multivariate model included the following further factors: antineoplasto-immunomodulating drug (OR = 0.47), combination therapy (OR = 2.00), biological drug (OR = 0.16), placebo-controlled trial (OR=0.50), extended indication (OR = 0.42), innovative drug (OR = 2.07). The area under the ROC curve was high, 0.77. Based on the external validation, using a model estimated on data until December 2010 and a cut-off point of 0.5, 79% of the reimbursement decisions in 2011-2012 were correctly classified. CONCLUSIONS: The new prediction model demonstrates in- ternal and external validity for 2011-2012. Therefore, the model could be used as input when further optimizing the market access strategy for products in clinical development.

RE2 A DETAILED COMPARISON OF DUTCH AND SWEDISH DRUG REIMBURSEMENT DECISIONS: WHAT EVIDENCE IS AVAILABLE, WHICH CRITERIA ARE USED, AND IS THE DECISION-MAKING PROCESS TRANSPARENT?

Franken MG1, Nilsson F2, Sandmann F2, de Boer A2, Koopmanschap MA3
1Faculty of Medicine, University of Hamburg, Hamburg, Germany, 2Helmholtz Zentrum München - German Research Center for Environmental Health, Neuherberg, Germany, 3Faculty of Dentistry, Rotterdam, The Netherlands, Dental and Pharmaceutical Benefits Agency, Solna, Sweden, 4University Universtity, Utrecht, The Netherlands
OBJECTIVES: To compare Dutch and Swedish drug reimbursement decisions and to investigate the available evidence, used criteria, outcomes and transparency of the decision making process. METHODS: We investigated Dutch and Swedish pub- licly available drug reimbursement dossiers from 2005 until July 2011. Applications and outcomes were compared and classified into different categories. For dossiers that included a full pharmacoeconomic evaluation (i.e. cost-effectiveness and/or cost-utility analysis) in both countries, we compared in detail how the available evidence was assessed to appraise societal value. RESULTS: Pharmacoeconomic evaluations were more often available in Swedish dossiers due to many exemp- tions in The Netherlands (mainly orphan and HIV drugs). Reimbursement dossiers only comprised a full economic evaluation in both countries. The reimbursement decision differed for four drugs, in which relatively more restric- tions were observed. Although Dutch dossiers provided more details, all dossiers included information of underlying clinical and economic studies. Comparators were always reported. Using a similar comparator (8x) resulted in a similar (5x) and a different (3x) therapeutic value judgement, while a different comparator (3x) resulted twice in a similar judgement. Swedish ‘yes’ decisions (10x) were judged cost-effective; ‘no’ decisions (two for one drug) were judged cost-ineffective. Dutch ‘yes’ decisions (9x, including two second decisions) were evaluated sufficiently (3x), reasonably (1x), moderately (2x), and insufficiently (3x) founded pharmacoeco- nomic evidence, all ‘no’ decisions (4x) were insufficiently founded. Appraisal ele- ments were descriptively reported. The (high) severity of the disease was explicitly mentioned in three overrating cases, and a high disease severity on the final ‘yes’ decision remained unclear. CONCLUSIONS: Both coun- tries make their reimbursement reports publicly available. Although the assess- ment is reasonable transparent, both countries could improve transparency of the appraisal process by more explicitly showing the actual role of each different (so- cial) criterion in drug reimbursement decision making.

RE3 HOW WILL THE NEW NHS CHANGES IN ENGLAND IMPACT THE IMPLEMENTATION OF RISK-SHARING SCHEMES FOR ONCOLOGY TREATMENTS? Jeffery M, Assimakopoulos M, White R
Acorn Partnership, London, UK
OBJECTIVES: With the current English NHS reforms will the new Clinical Commissi- oning Groups (CCGs) follow an Italian type regional approach to enable patient access to innovative and premium priced medicines when implementing patient access schemes. METHODS: We identified CCGs and their association with the local oncology networks, new commissioning decision processes and the practicality of implementing current patient access schemes. We also reviewed new schemes approved by the Italian medicines agency, AIFA, to accelerate reimbursement for new drugs espe- cially when there is limited availability at launch. RESULTS: It is clear that the suggested circa 200 proposed CCGs will have limited resources to fund suitable management structures to run risk share/patient access scheme effectively. Spend on pharmaceuticals, especially with public and physician demand, for innovative premium cost cancer treatments, will now be led and influenced by General Practi- tioners (GPs). The critical question facing family GPs will be how can they address the funding of these high cost treatments yet still satisfy patient demand. One policy that could be adopted was to introduce a risk sharing scheme, where the payer would be lead by AIFA who have developed an approach to enhance the reimburse- ment potential of innovative anti-cancer medicines. CONCLUSIONS: The new commissioning support bodies recently appointed by the English Department of Health’s, National Commissioning Board, could easily follow the Italian suggested decision processes to help provide decision frameworks to assess the economic and clinical impact of innovative medicines. The work is part of SerbianSP No41012.

RE4 BEYOND THE EVIDENCE - THE INFLUENCE OF DECISION PROCESSES ON OUTCOMES IN COVERAGE DETERMINATION OF HEALTH TECHNOLOGIES Fischer KE1, Rogowski WH2, Leidl R2, Stollenwerk B2
1Faculty of Medicine, University of Hamburg, Hamburg, Germany, 2Helmholtz Zentrum München - German Research Center for Environmental Health, Munich, Germany
OBJECTIVES: Coverage decision processes determine the accessibility of health technologies. Cost-effectiveness considerations have been identified to explain decision outcomes. Beyond the evidence, outcomes may be influenced by the process configurations used by decision makers. The aim of this exploratory study was to analyze the influences of transparency, stakeholder participation, scientific rigour of assessment and evidence judgments on decision outcomes in coverage decision-making. METHODS: Using survey data of 77 decisions from 13 countries, we examined whether outcomes differ by 14 variables that describe components of coverage decision-making and technology considered. To investigate the level of reimbursement, we analysed the likelihood of committees to cover a technology, i.e. positive (including partial coverage) vs. negative coverage decisions. We performed non-parametric univariate statistical tests and binomial logis- tic regression analysis. To identify differences on decision outcomes, we applied a step- wise variable selection procedure. RESULTS: We identified associations between the decision outcome and the following variables: the technology is a prescribed medicine (p=0.0097); the health condition is an endocrine, nutritional or metabolic disease (p=0.0311) and the judgment of the evidence after assessment (p<0.0001). The first estimation of the logistic regression model suggested a quasi-complete separation for those decisions where effectiveness and costs/cost-effectiveness...