PCN223
A COMPARISON OF MARKET ACCESS EVALUATIONS FOR NEW ONCOLOGY THERAPIES IN FRANCE, GERMANY AND THE UK: AN ANALYSIS USING THE PRISMACCESS DATABASE
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OBJECTIVES: In recent years (2011-2014) various new oncology therapies were launched and evaluated by the different market access authorities. The international Prismaccess database includes all evaluations and decisions by the respective authorities in France, Germany and the UK. **METHODS:** All decisions for new oncology therapies which were evaluated by the authorities in France, Germany and UK were systematically searched for. A comparison was executed with a focus on reimbursement decision, basis of decision, acceptance of submitted clinical endpoints, study designs, comparator, quality of life and indirect treatment comparison (ITC). **RESULTS:** In total there were 23 new oncology therapies being evaluated in the three countries. In France 10 decisions were positive (ASMR I-III), further 6 of minor improvement (ASMR IV), 20 were positive in Germany (n=3 'significant'; n=6 'considerable'; n=9 'minor'; n=2 'non-quantifiable' added benefit) and 4 were positive in England and 5 in Scotland. In 2 cases, respectively the assessment was positive (different magnitude) or negative in all countries. 26% (n=6) it was similar in at least three countries. (n=5 positive decisions; n=1 negative decision). In case overall survival was the primary endpoint the likelihood was higher in all countries for a positive decision. Key differences in terms of decisions were given in acceptance of ITCs, comparator as standard of care and ratings for cost-effectiveness. **CONCLUSIONS:** Using the Prismaccess database the analysis shows that there might be key differences in terms of evaluation criteria between the three countries analysed. In Germany a key focus is given on the appropriate comparator(s) and patient-relevant endpoints. In the UK and Scotland cost-effectiveness might trump a positive benefit assessment. In France the key drivers are not only the severity of the pathology (for tumours, 25% of SMR are not substantial), but also efficacy/adverse events ratio, Effective amount, Comparator choice and Therapeutic strategy.

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CURRENT STATUS OF REIMBURSEMENT DECISIONS FOR ORPHAN DRUGS OR CANCER DRUGS AND IMPLEMENTATION FOR ACCESS SCHEMES IN KOREA
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OBJECTIVES: Korean government has been making efforts to improve the access of orphan drugs or cancer drugs to patients since it is difficult for these drugs to be reimbursed due to its high price or lack of clinical evidence. We aim to investigate the current status of reimbursement and reviewed related schemes in Korea. **METHODS:** Appraisal results for orphan or cancer drugs during 7 years (2007~2013) were included and recommendation rate, final listing rate and order of entry among 8 countries were analyzed. **RESULTS:** Total 331 were recommended to be reimbursed in overall 467 appraisal results (71%), whereas 74 was recommended to be reimbursed among 121 results for orphan or cancer drugs (61%), indicating that it was less likely to be recommended for those drugs. Fifty eight orphan or cancer drugs (48%) were finally listed through NHIC negotiation process. For cancer drugs, recommendation and listing rate seem to increase from 47% to 64% and 32% to 48% (2008~2010 vs 2011~2013), respectively. Those drugs have been reimbursed in the 4.86th place among 8 countries including Korea on the average. Besides, 15 drugs considered as rule of rescue in those drugs have been listed for reimbursement. **CONCLUSIONS:** We identified that orphan or cancer drugs has been more accessible to patients as time goes. As the benefit enhancement plan for four major diseases (2013) and the Risk Sharing scheme (2013) have been implemented, it is expected for the coverage for those drugs in Korean National Health Insurance to be widened through these schemes.

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MARKET ACCESS LEVERS AND BARRIERS FOR KEY ONCOLOGY AGENTS IN THE EU5: SURVEYED ONCOLOGIST AND INTERVIEWED PAYER INSIGHTS
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OBJECTIVES: Health technology assessment (HTA), pricing and reimbursement (P&R) processes, and cost-containment strategies in France, Germany, Italy, Spain, and the UK, are increasingly stringent. This study explored the resulting impact on high-cost oncology brands, and carved out specific market access levers and barriers. **METHODS:** Across the EU5, 500 medical or hematological oncologists were surveyed regarding their current and expected prescribing patterns, and 30 payers who influence reimbursement at national or regional level were interviewed. **RESULTS:** Some 68-83% of surveyed oncologists in France, Italy, Spain, and the UK, and 44% in Germany report that the average time taken by their health care authority to review newly approved cancer treatments and settle reimbursement terms delays availability for prescribing by ≥6 months. Thereafter, country-specific prescribing restrictions impede uptake; e.g., 18% of German hematologists surveyed report that their indicative prescribing budget prevents use of ponatinib in >20% of their chronic myeloid leukemia patients, while 30% of Italian medical oncologists say the national oncology drugs register monitoring use of costly agents severely restricts prescribing of erlotinib and gefitinib for non-small-cell lung cancer. Interviewed payers stress, however, that well-designed pivotal trials considering increasing focus on added benefit over direct comparators will help optimize HTA and P&R terms, with those in Italy and the UK, especially, advocating cost-sharing schemes to secure market entry. Furthermore, demonstrable downstream cost savings, locally targeted marketing campaigns, and manufacturer estimates of patient population size to aid regional/local budget planning are specified as uptake levers. **CONCLUSIONS:** HTA and P&R demands and tightening budgets negatively impact prescribing of costly oncology brands in the EU5. However, clear demonstration of robust benefits over currently used agents, strategies such as cost-sharing to encourage payers to think beyond the price tag, and promoting familiarity with novel agents among regional and local payers will help optimize the market access opportunity.

PCN226
PRICING AND REIMBURSEMENT ANALYSIS OF BACILLUS CALMETTE-GUÉRIN (BCG) IMMUNOTHERAPY FOR BLADDER CANCER
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OBJECTIVES: The objective of the analysis was to assess the pricing and reimbursement possibilities, as well as the budget impact, of a new medicine for bladder cancer immunotherapy. **METHODS:** We investigated the number of medicines for bladder cancer immunotherapy that were registered and listed in the period between March 2011 and March 2014, in Serbia. We also made pharmacoeconomics analysis that would be a part of the Health Insurance Fund submission file. **RESULTS:** According to the European Association of Urology (EAU) Guidelines for non-muscle invasive bladder cancer (NMIBC) there are several bladder preservation strategies available: intravesical immunotherapy, intravesical chemotherapy, device-assisted therapy and combination therapy. In Serbia, there are three medicines listed for chemotherapy (doxorubicin, epirubicin and mitomycin) and one for intravesical immunotherapy (BCG). BCG has become the standard of care for high-grade NMIBC and carcinoma in-situ (CIS) and is superior to intravesical chemotherapy in reducing recurrences, in preventing or delaying progression of the disease. Radical cystectomy should be considered after BCG treatment failure, when BCG is contraindicated or not available. BCG is reimbursed in Serbia (wholesale price: 79,18€) but due to continuous shortages of registered BCG from May 2012, non-registered BCG was also listed (price: not defined). Still there was no import, due to worldwide shortages. The absence of the treatment encouraged the Serbian Institute of Virology, Vaccines and Sera "Torlak" to develop BCG for immunotherapy. As the price proposal for new medicine would be 55,43€, expenses per patient per year would be 498,87€ and total costs for 520 patients would be 259.412,40€, it is projected that total savings would be 111.150,00€ per year. Market share of domestic BCG would be 0,29% of total B list (hospital medicines) budget. **CONCLUSIONS:** The future aim is to develop, register and list domestic BCG that would provide lower costs per patient, high quality, availability and the continuous immunotherapy.

PCN227
THE EXPANDING VALUE FOOTPRINT OF ONCOLOGY TREATMENTS
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OBJECTIVES: To provide a better understanding of: how changes in the use of an oncology medicine can affect its aggregate value; how different HTA systems have assessed these value expansions; and whether there is a link between value expansions and use. **METHODS:** We examine all oncology medicines approved by the EMA between 2003 and 2005 – giving a sample of 10 medicines. Our framework sets out seven possible value expansions beyond an initial approved indication: different cancer type; different disease stage; different treatment line/stage; different treatment regimen; orphan designation; patient sub-population; and new route of administration. We then assessed how HAS (France), NICE (England and Wales), and Aetna (US) have recognised these value expansions. Finally, we analysed IMS data (2004-2013) on prices, volumes and sales for the five of the medicines. **RESULTS:** Seven of the 10 medicines in the sample have additional value expansions following initial indication. Many are now used for indications that are very different from their original indication. Most of the HAS assessments resulted in the drug being reimbursed but the rewards to the manufacturers were in many cases relatively low because few of the recommended drugs were given low "improvement in medical service" (ASMR) levels. The majority of NICE appraisals (63%) resulted in the drug/indication not being recommended for use in the NHS. Generally, the UK had lower prices, volumes and sales than France and the US (with some exceptions). The comparisons between France and the US were a little more equivocal. There is a mixed picture in terms of the correlation between NICE/HAS recommendations and sales in the UK/France. We observe a link between expansions in licensed indications and changes in sales. **CONCLUSIONS:** Health systems and policy makers need to recognise how product life-cycle considerations affect the value of medicines, and in particular, oncology medicines.

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IMPACT OF INTRODUCING COSTS/QALY THRESHOLD ON ACCESS TO ONCOLOGY MEDICINES IN SLOVAKIA
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OBJECTIVES: In December 2011, a threshold value of costs/QALY was introduced to Slovak legislation. The aim of this work is to assess its impact on inclusion of oncology drugs to the reimbursement system and their availability in clinical practice. **METHODS:** We evaluated the inclusion of oncology drugs to the reimbursement system based on data from the website of the Ministry of Health SR. We analysed the consumption of drugs based on the National Health Information Centre database. We acquired information about registered oncology drugs on the EMA website. We determined the level of availability of oncology drugs in clinical practice via a qualitative survey among oncologists. **RESULTS:** The success rate of including new oncology drugs in Slovakia was high in 2000-2011. From the 62 oncology drugs registered in this period by the EMA, 48 were included to the Reimbursement List. Innovative oncology drugs were included relatively quickly