**PHP212**

**OBTAINING OPTIMAL PERSONALIZED SURVEILLANCE STRATEGIES FOR PATIENTS WITH SCREEN-DETECTED COLORECTAL ADENOMAS USING DISCRETE EVENT SIMULATION**

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**BACKGROUND:** Colorectal cancer (CRC) screening in Spain uses a fecal-occult blood test (FOBT) for screening and colonoscopy as diagnostic tool. Adenomas constitute the predominant findings of this colonoscopy, and the removal of these premalignant lesions is considered the main contributor to the reduction of mortality and incidence of CRC. There is no clear agreement regarding the risk classification of adenomas as well as the optimal surveillance strategy for these premalignant lesions, and its characterization is crucial for improving the effectiveness of surveillance strategies by targeting individuals who would benefit the most. **OBJECTIVE:** To optimize, within a CRC screening program, surveillance of premalignant lesions using individual risk-based strategies, based on genetic analysis, that take into account benefits, harms and costs. **METHODS:** A discrete-event simulation model that reproduces the process of screening and takes into account the costs at every stage. From invitation to screening to surveillance of findings will be upgraded. The natural history of the disease will be included, with special emphasis on the events after adenoma detection at screening colonoscopy. Based on the results of a study at identifying common genetic variants associated with an increased susceptibility to develop colorectal adenomas, the risk of developing cancer or recurrent adenomas according to the clinical characteristics of the patients will be included in the model. The interval between surveillance colonoscopies will be optimized with the objective of minimizing the number of colonoscopies while keeping the same level of effectiveness, defined as the impact on incidence of advanced adenomas and cancer over time. **IMPLICATIONS:** Simulation models can help to test the effect of personalized screening strategies. Personalizing CRC screening through surveillance strategies may improve allocation of resources under cost constraints, minimize harms and maximize benefits of population-based programs, affecting millions of people.

**PHP213**

**FIXED REFERENCE PRICING OR BENEFIT ASSESSMENT OF ESTABLISHED PRODUCTS – FROM THE FRYING PAN INTO THE FIRE?**

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For nearly 25 years, the most effective tool for containing public spending on pharmaceutical drugs in Germany is the formation of fixed reference price groups (FRP) - the annual savings have continuously risen from 0.31 billion Euros in 1990 to 4.32 billion Euros in 2009. Hereunder, the so-called “jumbo groups” patent-free and priced controlled drugs, that were introduced in 2004 have been of high importance. With the recently published, first-time call for benefit assessments of substances in the established market (April 2013), the Federal Joint Committee (G-BA) has so far not yet launched another potent means of regulating market conditions. Unlike the early benefit assessment of new active ingredients where several substances had undergone scrutiny since January 2011, it is unclear what the outlook is for the benefit assessment of the established market. The decision of the government is to assess whether a FRP or a benefit assessment is preferred by pharmaceutical companies for established substances. Fixed reference price scenarios are calculated for therapeutically comparable substance classes within the call for benefit assessment of substances in the established market. For the established substances, a risk assessment and benchmark is performed based on the criteria in the code of procedure of the FJC and the assessment of new active ingredients, respectively. The results of the ongoing FRP scenario evaluation will be displayed as bar charts by savings in €. The risk assessment is displayed in a tabular format. From discussing the results of the FRP calculations compared to the benefit assessment of established substances, the presentation discusses implications for international reference pricing scheme. The German market has been regarded as the last bastion of free pharmaceutical pricing for a long time.

**PHP214**

**HTA NATIONAL PUBLIC POLICY AND THEIR SOCIO-ECONOMIC ENVIRONMENT: A EUROPEAN PERSPECTIVE**

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**OBJECTIVES:** Socioeconomic factors are important components of Health Technology Assessment (HTA) inferences in several countries. If we take the example of countries that have established HTA agencies, they required scientific expertise to emerge and become institutionalized. In a previous scientific work, we did an analysis of scientific inferences used in the HTA emergent countries and we observed that the lack of national research capacity and HTA institutionalization in a given country. **METHODS:** In order to explore endogenous as well exogenous factors sustaining HTA expertise, we undertake a principal component analysis as multivariate techniques in order to provide a group of dimensions that are most appropriate for the assessment of scientific expertise in the context of HTA public policy. **RESULTS:** HTA national public policy could be ranked according to their academic expertise. Country HTA publications productivity matched in countries with health expenses & gross product in several countries. Nevertheless this rank-

**PHP215**

**CLINICAL, EPIDEMIOLOGICAL AND ECONOMIC METRICS DIFFERENCE BETWEEN HPV-RELATED AND TRADITIONAL HEAD AND NECK CANCERS**

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**OBJECTIVES:** We compare smoking and alcohol consumption were the traditional causal factors in many head and neck cancers in the United States and Western Europe. However, the Human papilloma Virus (HPV) is now responsible for up to 80% of cancers of the oropharynx. HPV-related cancers appear to be associated with a higher risk of mortality and incidence of CRC. There is no clear agreement regarding the role of HPV in CRC. **RESULTS:** We compare smoking and alcohol consumption were the traditional causal factors in many head and neck cancers in the United States and Western Europe. However, the Human papilloma Virus (HPV) is now responsible for up to 80% of cancers of the oropharynx. HPV-related cancers appear to be associated with a higher risk of mortality and incidence of CRC. There is no clear agreement regarding the role of HPV in CRC. **CONCLUSION:** The goal of treatment has shifted from mortality to morbidity in these cancers. Measures of morbidity (functional status) are now important considerations in treatment options. This poster will compare and contrast various epidemiological method to determine the scope of HTA policies.

**PHP216**

**COMPARING THE VALUE OF DIFFERENT HTA DECISION MAKING PROCESS: EVALUATING THE VALUE OF THE SCIENTIFIC CONDITIONS OF HTA EMERGENCE IN THE SCIENTIFIC LITERATURE**

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**OBJECTIVES:** How health care decision makers arrange their appraisal process of new health care technologies has direct impact on population health and manufactures payoffs. This paper aims to explore endogenous as well as exogenous factors sustaining HTA expertise, we undertake a principal component analysis as multivariate techniques in order to provide a group of dimensions that are most appropriate for the assessment of scientific expertise in the context of HTA public policy. **RESULTS:** HTA national public policy could be ranked according to their academic expertise. Country HTA publications productivity matched in countries with health expenses & gross product in several countries. Nevertheless this rank-

**PHP217**

**THE FRAMEWORK FOR HEALTH ECONOMIC MODELING AND MULTI-CRITERIA DECISION ANALYSIS (MCDA) ON THE EXAMPLE OF THE MOBILE STROKE UNIT (MSU)**

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**OBJECTIVE:** The development of the evidence in early generation of a technology is a bottle neck for uncertainty in decision making. Health economic modeling can support the assessment of early innovation, but complex modeling approaches are criticized for being "black box" and in turn reduce their acceptance in health policy. **METHODS:** MCDA can address the gap about what matters to health care decision makers and data collection by explicitly structuring decision criteria. The combination of MCDA modeling and health economic modeling implies a potential for better budgeting of healthcare. This approach will be applied to the MSU, as it is analyzed regarding application of MCDA. **RESULTS:** Experts and stakeholders can support the: 1) Definition of model factors e.g. outcome parameter, which is generated as “stroke” (Barthel Index for Stroke outcome). 2) Value of the data valid? (outcomes of thrombolysis), 3) Model structure e.g. intersection, calculation parameters (stroke incidence, risk factors and population), 4) Validation of a model e.g. reassessment of step 1 - 3, and 5) Final analysis by using MCDA e.g. improved budgeting of health care. **CONCLUSION:** The integration of economic and medical combination is advantageous because simulation modeling as well as MCDA are a similar sequence of events. The simulation output, which is commonly validated by technical and medical experts, can gain validity by the heterogeneous perspectives of participating stakeholders in the validation process. For example, this raises
questions about priority and importance of certain outcome parameters like the thousand Euro threshold in the independence of patients after 3 months. The independence of patients after 3 months. The independence of the combination of MCDA and simulation modeling contributes to a transparent analytic process and results in a more complex understanding of the technology.

**PHP218**

**MECHANISM OF COORDINATED ACCESS TO ORPHAN DRUGS**
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Although the EU Council stated that “All health systems in the EU aim to make provision, which is patient-centered and responsive to individual needs”, unacceptable differences in access to orphan medicinal products (OMP) in the Member States of the European Union were identified. In the context of the 2010 Belgian EU presidency initiative on “Innovation and Solidarity” and within the framework of the process on corporate responsibility in the field of pharmaceuticals, EU Commissioner Tajani therefore foresees the necessity of developing a mechanism of coordinated access to Orphan Drugs. Designing a operational mechanism of coordinated access to OMP for patients, stakeholders and Member States to provide a transparent and effective process in line with the principle of the “real life access”. METHODS: The project is managed by Belgium (NIHD), supported by the European Commission and Eminent Thirteen Member States participated, with the stakeholders (AIM, EPI, ESIP, EFSAIM, CPM, EPIFIA, EGA, Europol, GIP). Three Workshops cover the different aspects of granting effective access to medicines: Identifying and assessing a relevant orphan drug (assessment/evaluation) - Selection of target population and mechanisms of funding (structural access) - Treatment (individual access). Feasibility of the prepayment opportunities for NICE development of desirable activities were studied, and no-go solutions were documented and rejected in order to develop implementable scenarios for pilot projects and policy recommendations. Discourse: Although coordinated access at an European level will be voluntary, some form of commitment from the participating partners is required. Moreover, it is crucial that the subsidiarity principle is not jeopardized or compromised; otherwise, no-go solutions will be avoided and previously made investments - in terms of financial and human resources, expertise and experience - (ex. by EUNet HTA, EMA COMP, EUERC, CAVOD,…) will be valorized.

**PHP219**

**THE FUNDING OF ORPHAN MEDICATIONS IN EUROPE: PAYERS’ ACHILLES’ HEEL?**
Bertelli A, Brown C, Johnson N, Spoor S

OBJECTIVE: To look at the affordability of orphan medications across Europe and whether payer attitudes to high-price medications are changing in the face of rising health care expenditure and tighter budgets. METHODS: A detailed review of 7 EU countries (France, Germany, Italy, The Netherlands, Poland, Spain, UK) was performed. The challenges at payer attitudes and funding decisions for key orphan drugs and the political, economic and societal impact of these. A key focus of the research was insight into payer attitudes towards the evidence base for the purpose of pricing negotiations and how anecdotal evidence, such as Patient Reported Outcomes (PROs) and patient case studies, have an impact on decision-making. Detailed research was also undertaken to ascertain the pricing levels achieved for a number of orphan drugs across Europe looking at payer thresholds and the implications of these for the purpose of reimbursement. RESULTS: The research demonstrates that there is considerable variation in pricing levels across the European markets and difference in payer attitudes. The main challenges of orphan drug reimbursement are around finding a balance between ensuring access for patients with unmet medical needs and for whom these solutions would otherwise be out of reach – in an affordable and sustainable way (“real life access”). METHODS: The project is managed by Belgium (NIHDI), supported by the European Commission and Eminent Thirteen Member States participated, with the stakeholders (AIM, EPI, ESIP, EFSAIM, CPM, EPIFIA, EGA, Europol, GIP). Three Workshops cover the different aspects of granting effective access to medicines: Identifying and assessing a relevant orphan drug (assessment/evaluation) - Selection of target population and mechanisms of funding (structural access) - Treatment (individual access). Feasibility of the prepayment opportunities for NICE development of desirable activities were studied, and no-go solutions were documented and rejected in order to develop implementable scenarios for pilot projects and policy recommendations. Discourse: Although coordinated access at an European level will be voluntary, some form of commitment from the participating partners is required. Moreover, it is crucial that the subsidiarity principle is not jeopardized or compromised; otherwise, no-go solutions will be avoided and previously made investments - in terms of financial and human resources, expertise and experience - (ex. by EUNet HTA, EMA COMP, EUERC, CAVOD,…) will be valorized.

**PHP220**

**BUDGET IMPACT AND THRESHOLDS: HOW ARE REAL DECISIONS MADE? - EXPECTED UTILITY OR PROSPECT THEORY?**
Adams R, Gray E, McCullagh L1, Schmitz S, Barry M, Walsh C1

1National Centre for Pharmacoeconomics, Dublin, Ireland 2First College Dublin, Dublin, Ireland Decision making rules in health technology assessments are often based on a fixed willingness to pay threshold for the incremental cost-effectiveness. This may be thought of as consistent with expected utility – with utility here defined in terms of Incremental Net Benefit (INB) – a combination of QALY gain and the threshold value. A number of alternative methods such as multi criteria decision analysis allow incorporation of other dimensions into the decision space. These seek to explore whether utility may be better captured by a more subjective approach rather than simple QALY approaches. These approaches were evaluated in a review of completed economic evaluations submitted to the Irish health care payer. Total spend on these was calculated using a combination of the payer reimbursement database and predicted budget impact. Real choices indicate that where the budget is small, there is no threshold but if the budget is large, there is a more likely to be reimbursement with a comparatively small QALY gain. Technologies in areas of cancer and orphan diseases often lie outside of the threshold where a technology would be accepted. Decision makers are faced with choices of varying degrees of risk. Choices associated with a low budget impact are deemed to be less risky. This pragmatic approach reflects a preference on behalf of the decision maker. Reality does not always match the ideal of a fixed threshold.

**PHP221**

**DOES HTA PROCESS HELP TO ACHIEVE THE HEALTH OBJECTIVES OF THE MILLENNIUM? A SOUTH AMERICAN ANALYSIS**
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1Axa Bio Consulting, São Paulo, Brazil, 2Federal University of São Paulo / Axa Bio Consulting, São Paulo, Brazil, 3Federal University of São Paulo, São Paulo, Brazil, 4CEASA/UnB, Brasilia, Brazil. OBJECTIVES: South America (SA) is a continent with 400 million people and occupies 12% of the world’s territory. It is composed by 12 countries and 6.75% of its population is below the poverty line, as defined by UN. The proper distribution of financial health resources, through an HTA process in public systems is potentially essential to improve the quality of health care expenditure. The objective of this study is to understand the incorporation process of new health technologies and compare the general health context of SA with the Millennium (OM). METHODS: A public data collection was performed in official sources linked to UN, to governments of SA and the Union of the Nations Surinamese (UNASUR). RESULTS: The public health financing in SA countries vary from 2.4% to 6.4% of the GDP, spending on health care is influenced by factors other than simple QALY gain. Prospect theory suggests that decision makers are concerned in practice with the ‘size’ of a given decision. This may be driven by factors other than simple QALY gain. Prospect theory suggests that decision makers are concerned in practice with the ‘size’ of a given decision.

**PHP222**

**THE NEW ITALIAN HEALTH CARE REFORM: INTRODUCING NEW MEASURES TO SPEED UP MARKET ACCESS**
Palmieri M1, Urbaniti D2, Lo Muto R1, D’Ausilio A1

1Creato-Ceutil, Milan, Italy, 2Creato-Ceutil, Luxembourg, Luxembourg OBJECTIVE: The Balduzzi law (189/2012) introduced several changes aimed at promoting the country’s development through a higher level of health protection and at bridging the gap left by the rationing of health care resource from the Spending Review (135/2012). Reducing the time to drug market access is one of the main purposes. The aim of the research was to analyze the actual law to understand its actual and future impact on the health care scenario. METHODS: An evaluation of the laws issued in the last three years that aimed at regulating the drug market was carried out. To build a future scenario analysis, we focused our attention on the Balduzzi law and two of the most promising regulatory measures. The new health reform can be potentially an interesting innovation to speed up market access, though the impact of including new drugs in the C class (at patient charge) before the price negotiations put off drug approved by AIFA and commercialized under the new regulation. RESULTS: The changes that will have a major impact on the drug market are: the allocation of the medicines approved under centralized procedure to the new C class between 60 and 90 days after the publication in the Official Gazzette of the European Union and the direct placement of generics and biosimilars approved by AIFA. The law changes will have a major impact on the drug market.

**PHP223**

**INVESTING IN EUROPEAN HEALTH R&D – A PATHWAY TO SUSTAINED INNOVATION AND STRONGER ECONOMIES**
Fonnas P1, Sakai O1, Urbina Valdespino E2, Delwart V3, Gissels S1

1DeLotte, Diegem, Belgium, 2Janssen Pharmaceutica NV, Beerse, Belgium, 3Yuill Consulting Europe, Brussels, Belgium A large number of factors point to an unavoidable rise in health care expenditure to 13%-18% of Europe’s GDP by 2030, even with policy interventions or budget cuts that aim to counterbalance these pressures. This growth in health care costs need not be undesirable especially so when higher spending on health care leads to improved health care quality and life expectancy. Therefore, the challenge is not “how do we reverse the growth of health care costs?” but “how can we best deploy the increasing resources spent on health care to create optimal benefits for the European population?” Health R&D is the key to being able to respond to this dilemma. Increased investment in R&D leads to improved health outcomes, long-term efficiency gains, better productivity and high economic yields. However, the outlook for Europe is not as positive as it could be. Recently, there has been a stagnation or even decline in European private and public investment in R&D, which is in sharp contrast with the much higher investments in the US. Private biopharmaceutical investments in health R&D, which are double the size of public health R&D, in 2011 actually declined in absolute terms. Public R&D investments declined or stagnated in most European countries and will be further under pressure in the near future. We will discuss a number of strategies that policymakers need to prioritize in order to better reinforce public R&D investments and adopt strategies that produce incentives for private enterprises so that the current decline in private sector investment is halted.

**PHP224**

**HOW DO ONCOLOGY DRUG PRICES VARY AROUND THE UNITED STATES, AND BRIC MARKETS?**
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