reimbursement methods, HTAs at the national level are more common.

**CONCLUSIONS:** Basic drivers of market access, such as health care spend, financing structure and regulatory policy create both independent and interdependent mechanisms that support access to new device technologies. Consideration of country level conditions and hurdles will inform device manufacturers’ differential strategies to enter established and emerging markets.

**PHP196**

**STAKEHOLDER INVOLVEMENT IN HEALTH TECHNOLOGY ASSESSMENT (HTA) OF NOVEL MEDICAL DEVICES**

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HTA as a medical device follows the path of drugs in many countries. There are however substantial differences that should be considered when evaluating medical devices. Drummond (2009) describes six important differences. Medical devices: 1) are often diagnostic therefore requiring to consider their related therapeutic effect; 2) their economic performance depend on users’ skills and complementary investments in training and equipment; 4) may cause a shift from one in-patient setting (operating room) to another (cathlab) or to an out-patient setting with substantial cost-effects; 5) are manufacturer specific, making it difficult to draw conclusions about product class effects; 6) innovation may be difficult to protect with patents thus encouraging imitation with resulting falling prices. In addition to issues 1-6, regulatory approval of a device does not require the same level of evidence as for drugs. Despite initial poor evidence, decisions on health care resource-use based on cost-utility (QALY) need to be made throughout the product lifecycle. This can be achieved by involving stakeholders in regular, timely data exchange for model updating, considering issues 1-6 above. As medical devices directly affect several stakeholders, their respective treatment costs from accounting systems can be used to inform the model. Updating the model improved the economic performance due to new devices and user learning is reflected (2-3). According to regulatory requirements manufacturers must evaluate their product performance and notify competent authorities of adverse events. Such data should update cost-utility evaluations relating to manufacturer specific patient morbidity (5). Further more as outcomes data are increasingly captured by devices directly or apps and electronically transferred to electronic health records, the burden on manufacturers to administrate registries may be lessened (2). As medical devices are regularly procured in tenders, their product prices should be used (6). In turn HTA outcomes should inform tenders.

**PHP197**

**OPPORTUNITIES AND LIMITATIONS OF SUSTAINABILITY INDICES IN SATISFYING THE NEEDS OF HEALTH TECHNOLOGY PURCHASERS SEEKING OBJECTIVE AND UNBIASED INDICATORS OF ENVIRONMENTAL AND SOCIETAL IMPACTS**

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**OBJECTIVE:** To establish the extent to which existing sustainability indices provide information that is transparent and relevant across cancer populations and for disease specific purposes for routine clinical practice.

Aims: We plan to develop national and international partnerships, and to advance the science of cancer treatment through research across the continuum of care and trials. Our goal is to foster common PROMs with multiple purposes, including performance and impact of cancer reporting, that will help deliver personalized quality care and treatment, and will concretely impact on cancer control and policy over the next five years.

**PHP199**

**THE IMPACT OF THE GERMAN PHARMACEUTICAL MARKET REORGANISATION ACT (AMNOG) ON THE GERMAN REFERENCE PRICE MARKET – TRENDS TWO YEARS AFTER THE INTRODUCTION OF THE AMNOG**

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With the introduction of the German Pharmaceutical Market Reorganisation Act (Gesetzes zur Neunordnung des Arzneimittelmarktes – AMNOG) in January 2011, pharmaceutical entrepreneurs have to present a dossier to demonstrate the additional benefit of a new pharmaceutical at product launch in the German market. Pharmacists failing to demonstrate additional benefit against the standard of care or corresponding indication must be included in the reference price group or even trigger the building of a new one. Top-selling reference price markets with many newcomers or price-aggressive competitors are at risk of a repeated examination through the federal joint committee (G-BA) in short intervals, resulting in a frequent updating of the reference price. This triggers a cascade, the so called “Kellertreppeneffekt” (Race to the Bottom), which could result in a rapidly decreasing reference price. One parameter of interest to assure an adequate security of supply is the measure value 160, assuring that at least 20% of packages and 20% of prescriptions are available at a lower price than the new reference price. To avoid the cascade, alternative, lower measure values, such as the measure value 100, can be applied. The measure value 100 is feasible for reference price groups with a large amount of products which are free of patients’ copayment. Pharmacists are normally free of patients’ copayment if the product price is 10% lower than the corresponding reference price. The focus of our presentation is to analyze the impact of the AMNOG on 10 top-seller reference price groups and to evaluate further adjustments to the reference price level of these groups through varying measure values. Furthermore, additional parameters of interest influencing the reference price level will be considered.

**PHP200**

**EVIDENCE FROM IRISH SURVEY DATA**

Coughlan D

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Health literacy (HL) research has mainly focused on the skills and abilities of individuals in the health care setting. For the past 20 years, most research has been conducted in North America. However, HL is now gaining political support at European Union level. This presentation is concerned with attitudes that nationally representative survey respondents in Ireland have towards improving their health by seeking a more health literate health care system. Two waves of the Survey of Lifestyle, Attitudes and Nutrition (SLAN 1998 & 2002) were used in this analysis. The primary focus of this study was to look across the socioeconomic gradient and see whether Irish health policymakers should invest in HL as a health inequalities or a public health issue. A secondary objective was to look at preventive health care utilization (General health check-up, blood pressure check-up, blood cholesterol check-up) using the HL variable as the main independent variable stratified by gender and medical card eligibility. The constructive dependent variable (termed ‘effective demand for a healthy literate health care system’) showed that 46% of respondents desired at least one attribute on a health literate health care system. Various multivariate logistic regression models used social class grouping, medical card eligibility, level of education and employment status as the main socioeconomic gradient variables. No discernible trend emerged among the socioeconomic variables. This suggests that HL should be viewed as a public health issue with a policy focus at a system level. Consistent with other studies (OR 1.15, 95% CI 1.04 - 1.28) were more likely than males to seek a health literate health care system. However, males without a medical card with an effective demand for health literate health care system were more likely to get a general check-up (OR 1.23; 95% CI 1.03 - 1.47). The investment in making the system more user-friendly would benefit all in society and not those stigmatized by having low literacy.