constitute a reward for manufacturers, however, various benefits have been reported such as reimbursement for drugs which received an initial negative recommendation (e.g. bortezomib and trabectedin, UK) and competitive advantage in the form of better formulation policy (sitaglipin & sitaglipin + metformin, USA); not to mention the possibility of granting discounts while leaving list prices untouched. Considerable administrative burden is placed on health care staff due to the diverse nature of schemes, the complexity linked with retrospective reimbursement, and lack of management capacity at current staffing levels.

CONCLUSIONS: Although evidence on the impact of MEs is patchy, the systematic literature review showed that there are already lessons to be learnt. Preliminary findings seem to suggest that MEs have indeed the potential of meeting payer, patient, and manufacturer expectations, yet important threats such as implementation difficulties, administrative burden and lack of management capacity need to be addressed.

OBJECTIVES: We aimed to explore the key organizational elements and the degrees of autonomy that is granted to Iranian corporized hospitals (trustees hospitals) affiliated to Ministry of Health after the Iranian health system decentralization reform. METHODS: All 18 Iranian corporized hospitals (that meet our criteria) involved to the study. In all, 27 Hospital Top Managers were interviewed (82% response rate). The semi-structured interview questions were developed using the framework method. The “framework” method was used for the analysis. RESULTS: Nine themes explain the key organizational elements including: decision right in “strategic”, “human resources”, “financial” and “physical resources” management, “product” and “process” orientation, “market expectations”, “residual claimant” and “social functions”. Decision right in “strategic”, “human resources” and “physical resources” management was very limited. The hospitals were permitted to generate revenue (fee-for-service) but weren’t the residual claimant, completely. The hospital was exposed to production of medicines but limited in procurement market (selling payment to market and financial accountability were the main accountability mechanism. Several insurance programs and governmental budget were used to protect poor people. CONCLUSIONS: We can see a kind of unbalanced and inconsistent autonomy. More decision right in “strategic” and “human resources” management, and procurement market should be granted, and also the hospital needs to be the residual claimant. Government needs a regulatory and accountability mechanism to guarantee hospitals performance and balance the revenue generating and social values objectives.

PHI155

REVIEW OF COST EFFECTIVENESS MODELS OF HIGH BUDGET IMPACT DRUGS

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OBJECTIVES: The recently made coverage decisions by UK’s NICE, Scotland’s SMC and Drug Reference Groups for the first time has led to the introduction of $1 billion budget impact drugs. In the United States, are strong indicators of trends in pricing and reimbursement that are likely to be observed in the future. To gain an additional insight into these trends, we analyzed the cost effectiveness studies for the top twenty highest selling drugs (~$90-100B worldwide sales). METHODS: The Top 20 drugs were selected based on their worldwide sales. For this analysis, we segmented these drugs into categories as primary care, specialty, small molecules, biologics, therapy areas and availability of generic alternatives. We analyzed the cost effectiveness studies that were published in peer-reviewed journals. Search was conducted using generic names of the drugs and the phrase “cost effectiveness” in abstract of the published study. RESULTS: During 2005-2010, the number of published studies on “cost effectiveness” has increased by more than 30%. There is a large variability in ICERs for same drugs for different indications, in some cases also varying by biomarkers. Primary care drugs had lower and less variable ICERs than specialty drugs. Variations also exist in methodology used by different groups in modeling cost effectiveness, especially for time horizon and comparator. Majority of primary care drugs were modeled for a time horizon of 35-40 years or lifetime to demonstrate cost effectiveness. CONCLUSIONS: This analysis shows the range, variability and methods used for calculation of ICER values for these high budget impact drugs and provides lessons for executives and policy makers.

PHI156

NOVEL DRUG REIMBURSEMENT MODELS: LESSONS AND IMPLICATIONS FROM CANCER DRUG REIMBURSEMENT SCHEMES

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OBJECTIVES: Cancer drugs are the world’s highest selling category of therapeutic products. Due to their premium cost and budget impact, several drug reimbursement models have been implemented worldwide by public and private payers. These models have potential implications for coverage and reimbursement of all branded products. This study reviewed recent cancer drug reimbursement models and developed lessons and implications for future products. METHODS: We reviewed cancer drug reimbursement schemes in developed and emerging markets. Interviewed payers and KOLs to develop lessons and implications for future products. RESULTS: Public and private payers worldwide have implemented several new models for cancer drug reimbursement to manage budgets and control costs. In the US, private payers are piloting single source compendia and third party protocols (eg. P4 Oncology) to limit off-label use of cancer drugs. In the UK, NICE has successfully negotiated lower price and discounts for first few cycles of therapy. In Italy, AIFA has implemented registry based postmarketing surveillance. In India, pharmaceutical manufacturers have implemented novel pricing strategy for first few cycles of therapy. In Germany, IQwig has proposed to use correlations between surrogate endpoints and patient relevant outcomes to determine value of cancer drugs. Due to increased cost pressure on payers, such models are likely to inspire novel reimbursement schemes for other branded products. CONCLUSION: Cancer drug reimbursement models are setting new benchmark for payers to manage access and control costs. These models have significant implications for other expensive branded products.

PHI157

USING THE CEAC FOR VALUE BASED PRICING: DON’T CHANGE THE GOALPOSTS

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ISSUE One approach under consideration for the proposed value based pricing of pharmaceuticals in the UK is to have different willingness to pay thresholds. However these are problematic to define, lack transparency and not readily understood by the wider public. OVERVIEW Different willingness to pay thresholds have been...
suggested as a way to incorporate uncertainty in the measurement of societal value when setting the price of a new pharmaceutical. An alternative approach would be to define the upper threshold for a 20% probability that the medicine is cost-effective at £30,000/QALY. In theory, where there is greater uncertainty, the ICER could be any value higher than 30k but at least there is a chance that the treatment is ‘cost-effective’ for a proportion of patients. Similarly in disease areas where there is low unmet need we could set the barrier higher and these medicines should have a probability greater than 80% of being cost-effective at that threshold. Setting all these on one set of goals, if you shoot from the penalty spot you have to score but from the half way line we can accept a few misses. CONCLUSION As a society we can remain consistent in what we are willing to pay for a unit of health benefit. For treatments where there is a high unmet need and an added benefit is perceived we can afford to be more risky.

PHP158 DETERMINING THE MONETARY VALUE OF A QUALITY-ADJUSTED LIFE YEAR (QALY): SYSTEMATIC REVIEW OF THE EVIDENCE

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OBJECTIVES: There are many thresholds for the value of a Quality-Adjusted Life-Year (QALY), varying between countries and jurisdictions, without however clear evidence of the valuation process. The objective of this study was to systematically review the literature for the evidence on the monetary valuation of a QALY.

METHODS: OVID MEDLINE® was independently searched for 1996-2011 by two reviewers using the keywords [QALY or (Quality and Adjusted and Life and Years)] and [Monetary and (Value or Value estimation or Value determination)]. Literature and data were hand extracted in 4 agreement. Included articles had to have applied a technique to determine the monetary value of a QALY, either on patients, the public, both, or through other statistical means.

RESULTS: From 174 articles yielded by the review, 6 met the criteria, 4 were European studies (Denmark, The Netherlands, the UK and Spain), and 1 from each the USA and China. None of them targeted only patients for the valuation, 4 targeted the general public, 2 studies focused on both. Three studies targeted a specific disease while 3 did not limit to any condition. Willingness-to-pay technique was the most common valuation method (5/6) and QALYs were determined with various direct or indirect elicitation measures. The average value for a QALY raised from the equivalent of less than US$8,000 to more than US$100,000. While some authors stated that preference valuation can lead to meaningful QALY values, the majority agreed on the large variability of the results depending on many factors such as income level, age, gender or disease condition and method of elicitation.

CONCLUSIONS: The literature on monetary valuation of a QALY is very limited, and the range of reported values is very wide and can be differently impacted by the survey tools used and by the characteristics of the population of interest.

PHP159 STRUCTURES FOR THE ROLE OF HEALTH TECHNOLOGY ASSESSMENT IN TRANSLATIONAL RESEARCH

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OBJECTIVES: Translational Research (TR) comprises activities aiming at the generation of biomedical knowledge, its transfer into clinical practice, and the take-up of research questions in biomedical research. It is described as a non-unidirectional process with mutual interchange between different development stages. Health Technology Assessment (HTA) is predominantly located in later phases of the translational process where implementation, diffusion and dissemination of a technology are focused. METHODS: Within the ELSA-GEN research collaboration, institutional and social aspects of TR in genomie medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that captures the potential feed-back loops HTA is involved in, and the characteristics of interactions with actors in TR. RESULTS: Traditionally, HTA is applied on a ‘societal level’ and aims at public and clinical decision-makers. But it can also be performed on a ‘project level’ to contribute in early phases of development by evaluating premature technologies. In that context, interactions of HTA with manufactures, clinicians and, to a less extent, (basic) researchers become relevant. Interactions are facilitated and shaped by specific organizational and institutional structures. These ‘modes of interaction’ include approval and reimbursement regulations, funding structures, stakeholder involvement in the HTA process, and prioritization of assessment topics. Formal prerequisites are not fulfilled between HTA and TR. Understood in terms of external price referencing and tenders at the wholesaler level in in-patient markets is confusing, and in order to make originator pricing more efficient, we suggest health technology assessment. As universal coverage is a priority, additional funding will be required with potential sources coming from competitive pricing landscape in Germany has significantly altered the implementation of AMNOG. Newer products would need to demonstrate improvement in comparative efficacy to command premium launch price or increase in price.

PHP160 INTRODUCING THE EUROPEAN NETWORK OF CENTRES FOR PHARMACOEPIDEMIOLGY AND PHARMACOVIGILANCE (ENCEPP): A BRIDGE BETWEEN MEDICINES REGULATION AND HEALTH OUTCOMES RESEARCH

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Attaining good patient health outcomes (HO) is the underlying purpose of any health care intervention, including drug therapy. The measurement of HO is the basis for evaluating the quality of health services, and a key element in determining the value of health interventions. Along with effectiveness, long term safety is an essential component of HO of new authorised human medicines. The explicit assessment of the sustained benefit-risk trade-off of new authorised products must be undertaken to ensure that unintended harmful consequences are not offsetting the intended clinical benefits. Spontaneous reporting schemes provide a means of monitoring surveillance of medicines that is important for raising early signals of safety concerns, but ad-hoc post-authorisation safety studies (PASS) may be necessary to evaluate the safety of medicines more accurately. The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP) is an initiative led by the European Medicines Agency aimed at further strengthening post- authorisation medicines research in Europe by facilitating the conduct of multi-centre, independent PASS focusing on safety and on benefit-risk. Specifically, ENCEPP provides a unique point of access for all involved stakeholders seeking collaboration for the commissioning or the conduct of PASS. This is achieved by offering access to available expertise and research experience in the fields of pharmacoepidemiology and pharmacovigilance across Europe brought together into a functioning network of expertise. It is anticipated that ENCEPP will add to knowledge and the EU capacity to conduct PASS studies in the light of shared methodological and expertise. In doing so, ENCEPP can serve as a bridge between medicines regulation and HO research in fostering risk/benefit management planning to minimise adverse events and maximise the benefit of marketed medicines.

PHP161 TOWARDS AN EFFICIENT NATIONAL DRUG POLICY IN THE RUSSIAN FEDERATION

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OBJECTIVES: Russia has a severe access to medicines problem. Of the 142 million people in Russia, only 20 million are eligible for outpatient medicines coverage as a part of the Supplementary Medicines Cover (DLO) programme. More than half of the eligible opt-out for cash. The current government’s goal is to eventually establish universal outpatient medicines coverage. This study explores pharmaceutical policy options for Russia to improve efficiency and access to medicines. We employ a conceptual framework to explain Russia’s priorities and the weighing of each health policy component in developing policy approaches. Based on Russia’s particular policy needs, as well as economic environment and market structure, we provide policy options anchored in lessons from the European Union and the United States. Overall, Russia requires more efficient pricing policies to increase coverage and access to medicines. METHODS: Our findings suggest that, although generic market shares are high, there is room for lower generic prices. In order to address this inefficiency, we propose the adoption of tenders for high-selling off-patent molecules, and free pricing for molecules with sufficient market competition. The introduction of external price referencing and tendering for in-patient markets is confusing, and in order to make originator pricing more efficient, we suggest health technology assessment. As universal coverage is a priority, additional funding will be required with potential sources coming from competitive pricing landscape. Understood in terms of external price referencing and tenders at the wholesaler level in in-patient markets is confusing, and in order to make originator pricing more efficient, we suggest health technology assessment. As universal coverage is a priority, additional funding will be required with potential sources coming from competitive pricing landscape.