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 a WTP in a threshold and then accept different levels of risk or a different probability of being cost-effective at that threshold. For example innovative products, cancer drugs and drugs for orphan diseases could be assessed with a more flexible approach based on the system already in place. For example we may be willing to accept only 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. For some 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 that have high unmet need 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 valuations 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 or Value (monetary estimation) or Value (valuation determination))]. Publications were excluded if their contents were not relevant to the study questions. Inclusion criteria were handled through 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 varied from the equivalent of less than US$6,500 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 ISLDA-GEN research collaboration, institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that captures the potential feedback 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 manufacturers, 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 by all TR actors and processes. Our analysis indicates that the perception and value of HTA varies highly. The full potential of HTA for the generation and translation of evidence in TR is not met. Feed-back of HTA results regarding evidence gaps into the research agenda could be strengthened. CONCLUSION: HTA can be regarded not only as a tool to promote successful TR, but also as an additional actor that influences the translation of a technology in different stages. Organizational and institutional structures need to be considered to foster its impact on the translation process.

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

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Attainment of 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 integral component of HO of new authorized 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 measure of unusual surveillance of adverse effects 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 excellence. It is anticipated that ENCePP will add to knowledge and the EU capacity to conduct PASS studies in the light of shared methodologies and expertise. In doing so, ENCePP can serve as a bridge between medicines regulation and HO research in supporting 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 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 prioritization of the above two factors could encourage the development and price of low-generic drugs. RESULTS: Russian pharmaceutical market will make an additional monetary unit to be invested in medicines rather than somewhere else in the policy environment have a positive effect on social welfare. CONCLUSIONS: Russia can achieve greater efficiency and lower prices in its pharmaceutical market, which would contribute to reaching the goal of universal outpatient medicines coverage.

PHP162 IMPACT OF AMNOG ON PHARMACEUTICAL PRICING TRENDS IN GERMANY

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OBJECTIVES: Understand the impact of AMNOG on pharmaceutical pricing trends. METHODS: The reforms implemented by AMNOG were reviewed by analysing recent changes in German healthcare system. A basket of five branded products was chosen to analyse pricing trends for past four quarters (Q3 2010, Q4 2010, Q1 2011, Q2 2011). Results: The basket experienced decrease in prices were compared for all five quarters. Some products such as Anarxep saw significant price decreases (5-9% per quarter), driven by AMNOG and by launch of cheaper biosimilar products. Other products show deflation of 0.6-1% per quarter. CONCLUSIONS: Pharmaceutical pricing landscape in Germany has significantly altered due to the implementation of AMNOG. Newer products would need to demonstrate in comparative efficacy to command premium launch price or increase in price.

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