payer management. **OBJECTIVES:** To better understand the current and evolving roles of CoE and national disease registries in the EU, including implications on the price and management of orphan drugs, and to identify implications for further evolution of rare disease specialty centers in the US. Trends on the EU development of CoE and national rare disease registries will be reviewed and expert opinion will be consulted. **RESULTS:** Tools and data that will be available to both the payer bodies and the CoE will be identified Examples of influence of CoE and disease registries on the pricing and reimbursement of orphan drugs (e.g. CoE in France, cancer registries in Italy) will be described. Implications of the use of this information and data will be explored for EU payers. **CONCLUSIONS:** EU payer bodies will gain increasing information and data necessary to further scrutinize the price and reimbursement opportunity for orphan drugs, through the use of registries and evaluation by CoE. Manufacturers should be prepared to understand and consider partnerships with CoE in EU.

PHP105

A REVIEW OF DIFFERENT APPROACHES PROPOSED FOR VALUE BASED PRICING

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Decision makers who undertake health technology assessments such as those conducted by NICE, deliberatively consider a new technologies cost per QALY, alongside other criteria (such as, equity, whether treatment is lifesaving and patient experience, etc) which are not captured in incremental cost-effectiveness ratios alone. The intention to implement an explicit value based pricing scheme in the United Kingdom in 2014 has sparked a debate regarding which elements should be included in the assessment of value and how they should be combined and traded-off against each other. Of importance is consideration to how values should be derived to determine how different criteria should trade-off each other. This debate is timely given that even where price is considered to be fixed during the re-imbursement process (such as the current NICE process) such systems could be seen implicitly determining value based price and may influence pricing decisions. Using an example presented in a recent review or multi-criteria decision making (Thokala 2011) we compare four mechanisms by which different elements of value could be explicitly and deterministically traded-off in order to provide an overall estimate of a value based price.**The mechanisms are:**conventional cost per QALY; MCDA; adjusted QALY approach; adjusted threshold approach; and a net benefit approach. Hypothetical criteria incorporated into the decision making process include equity, innovation, patient compliance and the quality of evidence. Using these examples, we show that these methods are clearly related in that they ultimately require estimates of monetary value to be placed on each dimension of value, but may place different emphasis on the weightings given to specific elements and the potential interactions between different elements. The mechanism in which these monetary values are derived, must importantly reflect societies values in trading off additional criteria for overall health gains.

PHP106

PRIORITY SETTING FOR HEALTH TECHNOLOGY ASSESSMENT IN UKRAINE

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OBJECTIVES: Under the concept of pharmaceutical branch development (2011-2020), social reimbursement system is going to be developed and implemented in Ukraine. That will demand a use of central health technology assessment (HTA) approach with appropriate instruments for its implementation. The aim of this publication was to develop an instrument for HTA prioritization in Ukraine by using qualitative approach. **METHODS:** A literature search was performed across PudMed, Medline, and Cochrane. EUR-ASSESS report was analyzed. Factors important for current health care decision making, data availability, and criteria important for prioritization in the other countries were reviewed by the experts and assessed on their applicability in Ukrainian health care setting. **RESULTS:** A list of criteria that should be a basis for HTA prioritization in Ukraine was developed. The criteria have different weight in accordance to their importance and data availability. These criteria are the following: burden of disease, current size of state financing for this health care branch, potential benefit of intervention for individual patient, disease prevalence, direct cost of intervention per patient, estimated budget impact, current rate of the technology use, inclusion of a medical product into standardized documents (clinical protocols, State formulary), additional aspects with an impact on health policy. **CONCLUSIONS:** Factors important for HTA prioritization in the other countries can not be used without adaptation due to differences in health care systems, current decision-making processes, and data availability. Developed prioritization instrument should be used as a tool for future health care insurance system in Ukraine.

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NEED AND IMPORTANCE OF PHARMACOECONOMIC GUIDELINES IN INDIA

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India's health care requirements are different as different systems of medicine are practiced. Only 15-20% of India's population has access to modern medicines (allopathic medicines) whereas remaining population uses traditional systems such as Ayurveda, Siddha, Unani, home remedies etc. People who have access to modern medicines have to spend out of pocket expenditure in order to have access to health care facilities including hospital, diagnosis and medicines. Out of these medicines are important for overall wellbeing population. Moreover only 10 % of population is covered by health financing schemes including medical insurance. Further a more than 1lakh (0.1 million) different brands of medicines flourish Indian market with sometimes more than a 100 brands of same molecule. The problem is manufacturers charge different prices for different brand names of same molecule. Medical practitioners have various options to choose from to prescribe these medicines and many a times it is observed that patients are given costly medicines when they can be given an economical alternative. This leads to financial burden on patients and health financing schemes including private and public sector. This is due to a lack of standard pharmacoeconomics guidelines in India. In presence of pharmacoeconomics guidelines it would be simpler to identify an economical alternative that would be beneficial to patient in particular and to society at large. In Asia countries like China, Taiwan, South Korea, Thailand have taken steps in formulating pharmacoeconomics guidelines. Even other developing countries like South Africa, Brazil, Mexico have taken steps to implement pharmacoeconomics guidelines. Country like India should take proactive steps in order to design and implement pharmacoeconomics guidelines.

PHP108

ANALYZING THE NEW ERA OF NATIONAL COVERAGE DETERMINATIONS (NCD'S) BY THE CENTERS FOR MEDICARE & MEDCAID SERVICES (CMS) POST ITS SIPULEUCEL-T DECISION

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OBJECTIVES: To review the various options that the Centers for Medicare & Medicaid Services (CMS) has to review new drugs and biologics under its National Coverage Determination (NCD) process, and conduct such review in the wake of its recent NCD for sipuleucel-T. This analysis seeks to better understand if CMS will employ NCD's to centralize its control over drug coverage. **METHODS:** NCD's have primarily been applied to drugs and devices that have had some associated issue that could result in product misuse. Such misuse may lead to unwarranted use, use that increases costs without commensurate outcomes, us that may impact patient safety or use outside of indication that is not deemed reasonable and necessary. Review of the most recent CMS NCD covering sipuleucel-T provides some indication as to how CMS may use its NCD authority to control product coverage. **RESULTS:** Analysis of past CMS NCD's indicates that CMS has historically regulated devices under NCD at a greater rate than drugs or biologics when there has been a concern over unwarranted use that would increase product utilization and costs over existing products. This has resulted in coverage and payment being either restricted or tied to other products. In the case of sipuleucel-T, CMS subjected it to review under NCD due to the fact that it is a vaccine, its cost is high and the high potential for use outside of castration resistant prostate cancer as reported in the media. The result of CMS' review was an NCD that allowed for coverage of on label use of sipuleucel-T, but reserved off label coverage decisions to individual contractors. **CONCLUSIONS:** Using CMS' sipuleucel-T NCD as a potential predictor of future NCD actions, CMS may continue to make overall coverage decisions regarding labeled indications, but defer off label coverage determinations to local contractors.

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DIFFERENTATIATOR FOR THE FUTURE: HEALTH TECHNOLOGY ENVIRONMENTAL FOOTPRINTS

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OBJECTIVES: A survey was conducted to establish the extent to which environmental factors impact payers and payer influencers, as well as macro-environmental policy and purchasing decisions. **METHODS:** Qualitative telephone interviews were undertaken with subjects in the UK, Germany, France, Spain and Sweden. **RESULTS:** Though still in their infancy, environmental consequences were confirmed as becoming an important dimension of health technology assessment (HTA). Regulation and best practice guidelines designed to limit the environmental impact of purchasing strategy were identified at local, regional, or national level in Sweden and the UK. Poor data availability was identified as a major challenge, undermining the credibility of claims related to environmental factors. To avoid a "green-wash" of health technologies presented to decision makers along the value chain, environmental evaluations will need to provide robust, standardized information concerning a wide range of criteria, such as waste management, energy containment or Carbon footprints. Health technology development, as well as market access management will have to anticipate an evolving awareness for environmental matters, in both emerging and mature markets. Their ultimate translation into policy and regulation is anticipated to be a combination of regulatory control and progressive application of Pigovian costs. **CONCLUSIONS:** Regulatory control is likely to be rolled out through updated operating procedures in existing structures, such as public agencies in charge of homologation, HTA or reimbursement. This is not likely to happen in a consistent manner across the various national healthcare systems. Payers are expected to deal not only with evolving enhanced recommendations and standards, but might choose to pro-actively reflect environment-related viewpoints themselves, when defining future specifications. In such a scenario, strategic purchasers will encounter a framework of versatile requirements and incentives, and are likely to opt for health technologies that are able to present a solid environmental case.