provide PE education, however the number of hours is sufficiently greater for schools with an elective (variable) course in PE. In addition, results pertaining to the opinions of key stakeholders on the influence of a number of hours devoted to PE-related topics and on enhancing PE education should be noted.

**PHP147 EARLY ACCESS PROGRAMMES (EAPs): REVIEW OF THE EUROPEAN SYSTEM**

Urbanić D, Trauni M

**OBJECTIVES:** Review the current status of Early Access Programmes (EAPs) in Europe, and discuss their implementation.

**RESULTS:** EAPs appear in all member states of the European Union (EU) and are considered a successful route to market for unregistered or investigational products. This is the case for Roche Pharma, Grenzach-Wyhlen, Germany, and Lash Group, San Bruno, CA, USA.

**CONCLUSIONS:** EAPs provide the possibility of making medicines available to patients in need before they are officially approved for use. However, the implementation of EAPs varies across Europe, with some countries having well-developed frameworks and others with less developed ones. Further research is needed to understand the impact of EAPs on patient access to new medicines.

**PHP150 SEARCHING FOR A THRESHOLD IN HUNGARY**

Börsi A

**OBJECTIVES:** Estimating the critical threshold value from previous reimbursement decisions is one of the several methods to determine a cost-effectiveness threshold. The methodology is based on analyzing the relationship between the Incremental Cost Effectiveness Ratio (ICER) of the assessed health technologies, and the reimbursement decisions. Our study tries to examine if there is any relationship between cost-effectiveness and decision making in Hungary by analyzing data abstracted from HTA appraisals and health economic studies.

**METHODS:** The members of the HTA Department examined the submissions containing a cost-utility analysis which were assessed by the Hungarian HTA Office since 2004. We created a database in which we summed up the cost/QALY values of the examined submissions and HTA reports. We analyzed the appraisal determinations of the HTA Committee regarding the assessed submissions in order to examine the likelihood of a positive/negative decision according the level of the assessed pharmaceutical's ICER value. We searched for the technology with the highest ICER value, which got reimbursed. RESULTS: We examined 165 submissions which contained a cost-utility analysis that have arrived to our Department. Our results suggest that there is only a weak correlation [r=0.14] between the level of the calculated ICER and the reimbursement decisions. We found, that the highest ICER which resulted a positive reimbursement decision was 9 500 000 HUF/QALY (32 000 EUR).

**CONCLUSIONS:** One of the several methods to determine a threshold value is to examine the relationship between previous reimbursement decisions and ICER values calculated in health economic appraisals. However one must take into account, that estimating a threshold value based on prior decisions has limitations, as reimbursement decisions are almost never made based on ICER ratios alone. This would be the main reason our study only showed a weak correlation between the level of calculated ICERs and the outcomes of the determinations.

**PHP151 THE INFLUENCE OF PATIENT COMPLIANCE ARGUMENTS IN NICE TECHNOLOGY APPRAISALS**

Brown AP1, Chaundhri D2, Guarnieri C3, Philips Z4

**OBJECTIVES:** To identify, using HTAInSite, if and how manufacturers have used improved patient compliance as a value argument for their product in submissions to the National Institute for Health and Clinical Excellence (NICE). We analysed if and how compliance data were presented, how they were received by NICE, and if compliance arguments were considered by the Committee, NICE have not explicitly stated to incorporate compliance as an influential factor in their final decision in any TAs.

**METHODS:** A key phrase search in HTAInSite was used to identify instances of ‘compliance’ and ‘adherence’ in manufacturer submissions and NICE technology appraisal (TA) documents. After review for relevance, information was extracted and used to conduct a qualitative analysis.

**RESULTS:** Fifteen manufacturer’s submissions and 12 TAs reported an improvement in compliance as a value argument for their drug. Factors used to justify improved compliance included improved convenience, a reduction in adverse events, increased treatment choice, and improved route of administration. In 8 of 13 TAs (relating to 11 manufacturer submissions), NICE state that the compliance argument was considered by the Committee. In the remaining 5 TAs, despite inclusion of a compliance argument by manufacturers in their submissions, the Committee made no reference to it in the TA. Interestingly, only three manufacturers explicitly reported evidence supporting their compliance argument; however, the Committee discussed this in all of the associated TAs. The impact of improved compliance on clinical outcomes or cost-effectiveness was frequently not clearly reported by manufacturers or NICE. NICE did not explicitly cite compliance as an influential factor in their final decision in any TAs.

**CONCLUSIONS:** The committee are more likely to consider a compliance argument if there is a clear clinical rationale and it is accompanied by supporting data. Although compliance arguments are considered by the Committee, NICE have not explicitly stated to have used them to influence final decisions.