

per bleed avoided: €1,029 to €18,128; or per Quality Adjusted Life Year (QALY) gained: from cost-saving to €1,538,460. Five studies applied long-term modeling, whereof three were based on a modification of the same Markov model. Modeling studies reported CE of prophylaxis from cost-saving up to €80,566/QALY. Evaluations with a time horizon of six and one year calculated ICERs of €466,346 and €1,538,460/QALY respectively. The underlying clinical evidence was overall weak. Presentation of model validation and analysis of uncertainty around the clinical evidence were limited in the modeling studies. **CONCLUSIONS:** Cost-effectiveness studies comparing prophylaxis and on-demand treatment in severe HA report strikingly conflicting results, from cost-saving to not cost-effective at all. Modeling studies show more consistent outcomes and stay within, or approach the reimbursement thresholds common in Western economies. Following guidelines for health economic evaluations in chronic conditions, results obtained with short-term time horizon have to be interpreted with caution; model validation should be a part of long-term CE analyses. Prospective observational studies based on wide utilization of identically designed patient registries form a high potential for strengthening clinical and health economic evidence in haemophilia.

## PSY141

## ABSENCE OF PRICE-PREVALENCE CORRELATION IN ORPHAN DRUGS IN ITALY

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**OBJECTIVES:** The present study analyses the annual therapeutic costs of drugs indicated for rare diseases in Italy, in order to verify if a correlation between costs and pathologies prevalence exists or not. **METHODS:** We screened all orphan drugs available in Italy in terms of annual cost and prevalence of the pathology. Drugs with different annual costs or used for a pathology without available data of prevalence were excluded from the analysis. As source of prevalence data we chose the website Orphanet. Overall, 49 orphan drugs were considered. Drugs were analysed according to price (lower than 100,000 euro each year or higher than 20,000), according to therapeutic class (onco-hematology, enzymatic deficiencies, pulmonary diseases) and according to classes of prevalence. **RESULTS:** The analysis of drugs with a therapeutic annual cost lower than 100,000 euro (n=38) showed no correlation between costs and prevalence. Similar results were obtained from drugs with a therapeutic annual cost higher than 20,000 euro (n=39). Even the analysis of orphan drugs sorted by therapeutic class (onco-hematology n=19, enzymatic deficiencies n=10, pulmonary diseases n=5) did not show a price-prevalence correlation. Similarly, no correlation was demonstrated classifying drugs into classes of prevalence. **CONCLUSIONS:** Criteria to assign the price to drugs are a strong matter of debate. Prevalence is generally considered one of the main criteria, thus to justify higher prices required by pharma companies marketing orphan drugs. Interestingly, none of the subgroups considered in our analysis showed any correlation between prices and prevalence. According to that, prevalence data can not be considered a main criteria adopted by AIFA in orphan drugs pricing.

## PSY142

## ANNUAL COST ANALYSIS FOR MEDICINAL PRODUCTS FOR RARE DISEASES IN BULGARIA

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**OBJECTIVES:** To evaluate the financial burden of medicinal products for rare diseases (MPRDs) for the Bulgarian healthcare system and to predict their future cost changes in the next 3 years. **METHODS:** Bulgarian Positive drug list (PDL) Annex 1, for ambulatory therapy, was compared with the List of MPRDs in Europe. The direct costs of therapy paid by the National health insurance fund (NHIF) for every INN was collected during 2013, 2014, and 2015 and were extrapolated for the next 3 years applying exponential and linear functions. **RESULTS:** In the Bulgarian PDL Annex 1 were included 7 out of 85 (8,2%) form Part I and 21 out of 132 (15,9%) MPRDs from Part II of EMA lists. Most of them are in ATC category A (8), B (6) and L (4) and the others are in C, G, H, J, N and V. The highest costs for the observed 3 years period were paid for antineoplastic and immunomodulating products (Etanercept, Rituximab, Adalimumab, Tocilizumab) - 71 655 443.20 euros, followed by medicines from ATC A category (Agalsidase beta, Imiglucerase, Sodium phenylbutyrate, Alglucosidase alpha) - 21 192 603.50 euros. The total costs for all MPRDs were 122 003 521 euros (6,2% of budget for PDL Annex 1). The equation  $y = 2E+07x + 3E+07$  was defined after linear extrapolation for the total costs and the expected cost changes for the next 3 years are calculated to be approximately 60, 70 and 80 million euro, respectively. **CONCLUSIONS:** The access to MPRDs in Bulgaria is limited as number of reimbursed products. The direct costs for MPRDs paid by NHIF are high for the Bulgarian healthcare system and the expectations are for cost increasing in the near future. Inclusion of generic MPRDs could lead to cost containment due to existing internal reference pricing in Bulgaria.

## PSY143

## KNOWLEDGE, ATTITUDE AND PERCEPTION OF JAPANESE ENCEPHALITIS AMONG HEALTHCARE STUDENTS OF MEDICINE, PHARMACY AND DENTISTRY OF A PRIVATE UNIVERSITY IN MALAYSIA

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**OBJECTIVES:** The objective of the study is to evaluate the knowledge, attitude and perception of medical, dental and pharmacy students in Private University (AIMST University) on the progress of Japanese Encephalitis. **METHODS:** A cross-sectional observational study on a convenient random sample of 252 students from AIMST University by using pretested and validated questionnaires to gather information

on the attitude, knowledge and perception of medical, pharmacy and dental students. **RESULTS:** From total 252 respondents, 75 were male (29.8%) and 177 of them were female (70.2%). For evaluation of knowledge and perception, males (Mean rank = 10.53±2.91) were having less adequate knowledge than females (Mean rank = 11.02±2.88). Among all races that participated in the study, Indians were having the most adequate knowledge than other races on Japanese encephalitis (Mean rank = 33.25 ±5.29). Among the Faculty of Medicine 70 (27.8), Pharmacy 100 (39.7) and Dentistry 82 (32.5), Faculty of Pharmacy was having the most adequate knowledge than other faculties (Mean rank = 10.97±2.81). Year 4 and Year 5 respondents were having almost same percentage of adequate knowledge that was (Mean rank = 32.69 ±4.84) and (Mean rank = 32.99 ±5.02) respectively. Non-hostellers (Mean rank = 31.93 ±4.12) were having less adequate knowledge than hostellers (Mean rank = 32.70 ±5.12). For educational background, respondents from A-Level (Mean rank = 35.90 ±5.56) were having the most adequate knowledge. **CONCLUSIONS:** Overall good knowledge was seen in the students of AIMST University about Japanese encephalitis. The pharmacy students were having good knowledge as compared with the other faculties in the university.

## PSY144

## SOCIETAL IMPACT OF PAIN (SIP) 2016 - 8 POLICY RECOMMENDATIONS: TIME FOR ACTION

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**OBJECTIVES:** About 250 representatives of healthcare- and stakeholder-organisations from 28 countries met in Brussels in May 2016 to: raise awareness of the relevance of the impact of pain on societies, health and economic systems exchange information and share best-practices across all member states of the European Union and foster European-wide policy strategies & activities for an improved pain care in Europe. The scientific framework of the SIP platform is under the responsibility of the European Pain Federation EFIC®. Cooperation partners for SIP 2016 are the Pain Alliance Europe (PAE) and Active Citizenship Network (ACN). Grünenthal GmbH is responsible for funding and non-financial support. **METHODS:** SIP 2016 hosted four working groups to discuss: Pain as a quality indicator for health care Chronic pain: a disease or symptom? The relevance of pain in cancer care and rehabilitation Pain, rehabilitation and reintegration of workers in the workforce The faculty of each working group produced specific policy recommendations addressing the societal impact of pain (SIP). **RESULTS:** The organizing partners formulated eight key recommendations directed to the institutions of the European Union and national governments: **Implementation of article 8.5 of the Cross-border Healthcare Directive Establish an EU platform on the societal impact of pain Integrate chronic pain within EU policies on chronic diseases Ensure that pain care is a part of policies and strategies on cancer Initiate policies addressing the impact of pain on employment Implement workplace adjustments for people with chronic pain Increase investment in pain research Prioritize pain within education for healthcare professionals, patients and the general public** **CONCLUSIONS:** The policy recommendations form a comprehensive base for further policy development for the management of the societal impact of pain.

## PSY145

## HOW DOES THE ADDITIONAL BENEFIT EXTEND OF ORPHAN DRUGS IMPACT PRICE NEGOTIATIONS IN THE GERMAN OUTPATIENT SECTOR?

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**OBJECTIVES:** For orphan drugs an additional benefit is granted by market authorization of the European Medicines Agency.[1] Although an additional benefit is granted companies have to demonstrate the extent of additional benefit as basis for subsequent reimbursement price negotiations by submitting a simplified dossier to the Federal Joint Committee (Gemeinsamer Bundesausschuss).[2] The objective of this analysis was to assess whether the additional benefit extent of orphan drugs does impact rebate size of price negotiations. The hypothesis indicated an inversely proportional association between additional benefit extend and negotiated rebate size. **METHODS:** In a first step the orphan drug market was analyzed and substances affected by an assessment of additional benefit extent were identified within the German healthcare market. Association between additional benefit extent and rebate size of negotiations was analyzed by Spearman correlation. Data were collected from public available information of the Federal Joint Committee as well as price information from the German pharmacy pricing data base LAUER-TAXE.[3] In a second step of the analysis a survey was conducted and market access experts of orphan drug manufacturers were interviewed. **RESULTS:** By February 2016, 84 orphan drugs with orphan drug designation were identified in the European Union. 19 were distributed in the outpatient German healthcare market and underwent additional benefit extent assessment and price negotiations. Association between additional benefit extent and rebate size could only be identified if the category "not quantifiable additional benefit" was excluded. **CONCLUSIONS:** There is only limited association between the extent of additional benefit and rebate size for orphan drugs. This is caused by a large rebate range for orphan drugs for which the additional benefit extend was not quantifiable. [1] European Community, Regulation (EC) No 726/2004. [2] Gemeinsamer Bundesausschuss, Nutzenbewertung nach § 35a SGB V, 1.06.2015: <https://www.gba.de/informationen/nutzenbewertung/>. [3] LAUER-TAXE®, 01.06.2015.

## PSY146

## ELEMENTS OF ORPHAN DRUGS VALUE

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