in 10,000 inhabitants. Although individually rare, together, rare diseases affect significant part of the population. Therefore, patient access to orphan medicines is receiving increasing political attention in the United States and Europe. The objective of this study was to assess the impact of orphan drugs on medical utilization and costs in Serbia. METHODS: Serbia’s Reimbursement List has been reviewed and identified orphan medicines were crossed with the List of orphan drugs in Europe, published in July 2011, available from the European Medicines Agency (EMA) online database. A systematic analysis of regulatory trajectories was based on a review of official documents setting out legislation regarding rare diseases and orphan medicines in Serbia. RESULTS: Only 6.5% (4 out of 61) of authorized orphan medicines in Europe had a designation and 17% (65 of 385) of pertinent orphan designation were available and reimbursed in Serbia. According to the first level of the ATC Classification System, most of reimbursed orphan medicines belonged to the group L – Antineoplastic and immunomodulating agents. It is estimated that there are approximately 500,000 patients suffering from rare diseases in Serbia. Although the National register for rare diseases does not exist, the Law on Health Care provides for the forming of the official centers of reference for rare diseases that have the obligation of diagnosing, treatment and patient counseling, but also of creation of National register. Neither policy measures nor research incentives for rare diseases exist in Serbia. CONCLUSIONS: The low share of reimbursed orphan drugs in Serbia may be due to incomplete compliance with legislation of EU and existence of domestic procedure for authorisation. The EU policy on treatment of rare diseases facilitates the penetration of orphan drugs on the EU market, but apparently there is also considerable budget impact on the availability of orphan medicines.

PSY76 OPIOID AND ANTIPEPTIDE DRUG UTILIZATION AMONG PATIENTS WITH CHRONIC NEUROPATHIC PAIN CONDITIONS

Abdulbas A1, Parsons B2, Schaefer C3, Mann R4, Daniel S5, Bai R6, Nalamachu S7, Romanelli R8, Stacey BP9, Anschel A1, Tuchman M10

1Purdue Pharma L.P., Stamford, CT, USA, 2Purdue Pharma L.P., Stamford, CT, USA, 3Purdue Pharma L.P., St. John’s, TX, USA, 4Saint Helena Island, SC, USA

OBJECTIVES: Opioid use among patients with chronic neuropathic pain is associated with health care utilization and costs. This study calculates updated, payer-specific estimates for opioid-related overdoses accounting for over 16,500 deaths per year. METHODS: The FDA granted 1558 orphan designations and 1949 approvals (9.6% of designated products), and the EMA 935 designations for 639 different products and 149 approvals (6.9% of designated products), and the EMA 935 designations for 639 different products and 88 (9.4%) approvals during the study period. The time for OD designation to approval was estimated. CONCLUSIONS: The presence of orphan designation to approval was estimated. The FDA and EMA online databases for the period 2000-2011. The FDA granted 1558 orphan designations for 1133 different products, and 149 approvals (9.6% of designated products), and the EMA 935 designations for 639 different products and 88 (9.4%) approvals during the study period. The time for OD designation to approval was 2.74±2.39 years in the FDA and 3.91±1.99 years in the EMA (p<0.05). EMA approved a larger number of designations (15.2%) than the FDA (12.3%) for the 569 products designated by both agencies; 67% of these products were first designated by the FDA and 78% of the 50 products approved by both agencies were approved first by EMA (p<0.001). CONCLUSIONS: The time for OD designation to approval was estimated. A restrictive time frame of 5 years was used for the 569 products with orphan designation to approval time frame of 5 years was used for the 639 products with orphan designation to approval. The FDA and EMA time frame from the first OD designation to approval was estimated.

PSY77 QUANTIFYING THE IMPACT OF DIFFERING MEASURES USED TO STUDY PERSISTENCE AND ADHERENCE WITH THE INFUSIBLE ANTI-INFLAMMATORY BIOLOGIC INFliximab: UTILIZATION FROM REAL-WORLD MEDICAL PRACTICE

Romanelli R1, Lehaly A1, Jukes T1, Ellis L2, Ingham M1, Ishiaka D2

1Sutter Health, San Francisco, CA, USA, 2Yassens Scientific Affairs, LLC, Horsham, PA, USA

OBJECTIVES: Evaluation of measures of medication-taking behavior is important with infusible anti-inflamatory biologic agents. This study evaluated persistence and adherence measures from utilization data on the infusible anti-inflammatory biologic infliximab. METHODS: Patients were identified through the electronic health records (EHR) with ICD-9 diagnoses of rheumatoid arthritis (714.0), psoriatic arthritis (714.5), and ankylosing spondylitis (715.0) for at least 1 year for DPN, strong short-acting opioids were the most frequently used opioid class, ranging from 14.3% in DPN to 5.7% in CLBP. CONCLUSIONS: Patterns of opioid use observed in this study were not fully consistent with published guidelines, opioid use was highest among diabetes patients between January 1, 2007 and June 30, 2011, >18 years of age, with ≤1 maintenance dose were included. Infliximab dosing data were extracted from medical chart review and the EHR. We employed Kaplan-Meier (KM) analyses to estimate median time to treatment discontinuation and Cox regression to estimate factors associated with discontinuation. Medication possession ratio (MPR) was calculated as sum of prescribed infusion frequency intervals divided by days from first infusion to last infusion. Compliance was defined as MPR ≥80%. Proporition of days covered was also explored (data not shown). Sensitivity analyses were performed for various definitions of “treatment gap” and “discontinuation”. Analyses are shown one-time questionnaire, and investigators completed a case report form based on a 6-month retrospective chart review. Pain severity was based on the Brief Pain Inventory average pain score. RESULTS: A total of 624 subjects were enrolled: 71% were Caucasian, 55.4% were females, and the mean age was 55.3 years since NeP diagnosis. The proportion of patients with each NeP indication was similar (16.0%-17.9%). Pain severity was mild, moderate, and severe in 17.6%, 47.6%, and 32.2%, respectively. The most frequently used NeP medications over the past 6 months were opioids (53.0%) and AEDs (49.0%), ranging from 33.0% (DPN) to 81.1% (CLBP) for opioids, and 28.3% (CLBP) to 64.1% (SCI) for AEDs. Overall, AED use remained unchanged across pain severity categories (46.4%-50.5%), while opioid use increased significantly with greater pain severity. 28.2% mild, 53.2% moderate, 65.2% severe (p<0.0001). Opioids were used by substantially proportion of patients across all pain severity levels including 33.3% in SCI, 50.0% in DPN, 40.9% in CLBP, and 37.5% in BPN. CONCLUSIONS: A high share of reimbursed orphan drugs in Serbia may be due to incomplete compliance with legislation of EU and existence of domestic procedure for authorisation. The EU policy on treatment of rare diseases facilitates the penetration of orphan drugs on the EU market, but apparently there is also considerable budget impact on the availability of orphan medicines.
OBJECTIVES: Managed care companies implemented step therapy (ST) policies to reduce utilization of opioids in new patients. The purpose of this analysis was to compare market shares for opioid products for plans identified with and without ST policies in the US. METHODS: A retrospective claims database study was conducted using the MarketScan Commercial and Medicaid Database. Avastin, Bevacizumab, and Herceptin were included. RESULTS: A total of 9,915,969 patients having their first prescription in 2009 were evaluated. CONCLUSIONS: These results were consistent with the finding of greater intention to perform protective behavior when using OTC acetaminophen products. Educational interventions targeting appropriate use of OTC products as per the Drug Facts panel could promote risk cognition, and thus intensify consumer intention to perform protective behavior.

PSY81
EXAMINATION OF TREATMENT PATTERNS OF ANKYLosing SPONDYLITIS PATIENTS IN THE VETERANS AFFAIRS AND MEDICARE DATABASES USING A VISUALIZATION TOOL
Xie L1, Du J1, Wang L1, Yuce H1, Raser O2
1STATinMED Research, Ann Arbor, MI, USA, 2STATinMED Research, Dallas, TX, USA, New York City College of Technology, CUNY, New York, NY, USA, 3STATinMED Research/The University of Michigan, Ann Arbor, MI, USA

OBJECTIVES: To examine treatment patterns of ankylosing spondylitis (AS) patients who initiated anti-tumor necrosis factor (TNF) and non-TNF biologic agents, via a visualization tool. METHODS: Patients with at least one AS diagnosis were identified from the Veterans Health Administration (VHA) Medical SAS and Medicare claims datasets. Patients identified from the VHA were required to be at least 18 years old, and those from Medicare at least 65 years. AS patients who initiated therapy with anti-TNF and non-TNF biologic agents were identified. Switches from an anti-TNF to a non-TNF or vice versa within two years after initial treatment were examined. Initial treatment continuation rates and discontinuation rates were also calculated. Patients using at least two treatments were identified using a processing language and illustrated in a data visualization tool. RESULTS: In the Medicare sample, 1159 AS patients initiated at least one TNF, of which 1,689 switched to another anti-TNF and no patients remained on their initial therapy. A total of 532 AS Medicare patients initiated a non-TNF, of which 1.5% switched to an anti-TNF, and only 3.9% remained on the initial therapy. In the VHA sample, 1021 AS patients initiated therapy with an anti-TNF, of which 1.5% switched to another anti-TNF type, 49.56% discontinued therapy and 36.73% remained on their initial therapy. A total of 84 AS patients from the VHA initiated non-TNF therapy, of which 5.7% switched to an anti-TNF and no patients remained on their initial therapy. CONCLUSIONS: Patients who initiated anti-TNF therapy were more likely to remain with this therapy. The VHA sample had a higher switching rate than the Medicare sample. Data visualization tools can help researchers with analyzing and summarizing clinical patterns up to two switches identified using a processing language and illustrated in a data visualization tool.

PSY82
THE CHALLENGE OF ACCESSING ORPHAN DRUGS IN THE MIDDLE EAST: A CRITICAL REVIEW
Almalki A1, Alameri A2, Gun J3, Kelton CM4
1University of Cincinnati College of Pharmacy, Cincinnati, OH, USA, 2University of Cincinnati, Cincinnati, OH, USA, 3Business, Cincinnati, OH, USA, 4University of North Carolina, Chapel Hill, NC, USA

OBJECTIVES: An orphan drug is a drug developed specifically to treat a rare medical condition. It is unclear how well rare-disease patients in the Middle East are able to obtain orphan drugs. In this study, we provide a critical review of the standards for orphan drugs in the Middle East. METHODS: Using Medline and other internet-based search engines, a critical review of both English and Arabic literature and other documents was performed and evaluated 1) the prevalence of rare diseases in the Middle East; 2) problems with obtaining orphan drugs in the Middle East; 3) availability of orphan drugs in the Middle East; and 4) development by pharmaceutical companies of orphan drugs for Arab diseases. RESULTS: Approximately 2.8 million patients are estimated to be suffering from a rare disease in the Middle East. Genetic disorders such as haemoglobinopathies, glucose-6-phosphate dehydrogenase deficiency, and autosomal recessive syndromes have a presence throughout the Middle East, with the latter’s occurring in approximately 1 out of 3,500 newborns. The prevalence of Behcet disease was estimated to be 0.23, 1.35, and 1.25 per 100,000 in Bahrain, Kuwait, and Oman, respectively. To help with diagnosis, the Centre for Arab Genomic Studies has constructed a rare-disease database. Despite the high expense of orphan drugs, some health care companies, such as Taibah, currently market and distribute orphan drugs. The Dubai Biotechnology & Research Park provides an environment for life sciences companies to work in the Middle East. CONCLUSIONS: In order to promote the treatment of rare diseases, Middle Eastern governments need to facilitate education and training of health care personnel; develop and execute a method for obtaining and paying for orphan drugs; and provide tax, marketing, and other incentives to domestic and international firms to develop drugs specifically for the diseases of most importance to Middle Eastern patients.

PSY83
HEALTH CARE RESOURCE UTILIZATION PATTERNS ASSOCIATED WITH BELLMINAM IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: RESULTS FROM OBSERVATORY STUDY IN THE UNITED STATES
Narayanam S1, Dall’Era M2, Collins C2, Dennis O2, Oglesby AE2, McGuire M2, Pappu R2, Motley O3, Keenan O2
1IPSOIS, Columbia, MD, USA, 2UCSF, San Francisco, CA, USA, 3Medstar Washington HospitalCenter, Washington, DC, USA, 4UCB, Atlanta, GA, USA, 5GliaanSmithKline, Research Triangle Park, NC, USA, 6Medical Data Analytics, Parsippany, NJ, USA, 7GliaanSmithKline, Philadelphia, PA, 8Medtemune, Gaithersburg, MD, USA

OBJECTIVES: Risk cognition of children and adolescents was measured using a 7-point Likert scale where 1=strongly disagree and 7=strongly agree. Spearman correlations and multiple linear regression analyses were performed controlling for demographics, usage characteristics, and attitude towards the use of OTC products. RESULTS: A total of 200 completed surveys were obtained. Items measuring intention to perform protective behavior showed strong internal consistency (Standardized Chronbach’s alpha=0.8). Mean intention towards protective behavior (4.9 ± 1.3 was measured. The mean age of the patients was 13.2 ± 3.9. RESULTS: A total of 200 completed surveys were obtained. Items measuring intention to perform protective behavior showed strong internal consistency (Standardized Chronbach’s alpha=0.8). Mean intention towards protective behavior (4.9 ± 1.3 was measured. The mean age of the patients was 13.2 ± 3.9. RESULTS: A total of 200 completed surveys were obtained. Items measuring intention to perform protective behavior showed strong internal consistency (Standardized Chronbach’s alpha=0.8). Mean intention towards protective behavior (4.9 ± 1.3 was measured. The mean age of the patients was 13.2 ± 3.9. RESULTS: A total of 200 completed surveys were obtained. Items measuring intention to perform protective behavior showed strong internal consistency (Standardized Chronbach’s alpha=0.8). Mean intention towards protective behavior (4.9 ± 1.3 was measured. The mean age of the patients was 13.2 ± 3.9. RESULTS: A total of 200 completed surveys were obtained. Items measuring intention to perform protective behavior showed strong internal consistency (Standardized Chronbach’s alpha=0.8).