time, medical/surgical complications to refine a robust measure of effectiveness useful to perform cost effectiveness analysis.

PSY97
CHARACTERISTICS OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) CURRENTLY ON REMISSION, WITH ACTIVE DISEASE BUT NOT EXPERIENCING FLARE, AND THOSE EXPERIENCING FLARES IN CLINICAL PRACTICES IN EUROPE
Narayanan S[1], Hutchings R[2], Lu Y[2]
[1]Ipsos Healthcare, Columbia, MD, USA, [2]Ipsos Healthcare, London, UK
OBJECTIVES: To assess the characteristics of SLE patients currently on Remission (Group-1), currently with active disease but not experiencing a flare (Group-2) and those who are experiencing flares (Group-3) in Europe (EU). **METHODS:** A multicenter medical chart review of adult (16-89 yrs) SLE patients was conducted in 1Q2014 among rheumatologists/internal medicine physicians in UK/France/Germany/Italy/Spain (5EU). Physicians were recruited from a geographically representative sample in each country. Approx. 5 consecutive eligible persistent active or relapse remitting SLE patients currently managed as part of usual care were identified. Physicians abstracted de-identified patient data on disease characteristics, lab values and treatment patterns. Patient disease status and humanistic burden was assessed by physician per clinical judgment & patient interaction. **RESULTS:** 747 SLE patient charts were abstracted in 5EU (UK: 156/France: 149/Germany: 148/Italy: 146/Spain: 148); Group-1: 25.7% (range: 19.9% (Italy) –29.7% (Germany)), Group-2: 56.2% (range: 42.3% (UK) –66.4% (Italy)), Group-3: 18.1% (range: 13.5 (Germany) –28.8 (UK)). Patient characteristics included (Group-1/Group-2/Group-3): age (yrs): 41.4/43/40.6; % female: 81.8/80.2/77.8; % full-time employment: 38.0/34.5/32.6; % part-time employment: 25.5/20.5/17.8; % on sick leave: 3.6/7.6/17.0; % currently receiving treatment in in-patient setting: 3.1/7.6/28.1; % hospitalized >=1 in past-year: 23.4/32.1/55.6. Top-5 organ manifestations were (% Group-1/Group-2/Group-3): musculoskeletal: 90.6/89.5/88.1, mucocutaneous: 86.5/84.0/85.2, haematologic: 45.8/53.8/55.6, renal: 23.4/26.7/33.3, pulmonary: 15.1/13.6/26.7. In Group-1/Group-2/Group-3, % patients with low C3 and C4 were 33.3/53.9/73.4 and 31.6/53.2/77.5 and % anti-ds-DNA positive were 54.7/71.0/78.5. Humanistic burden (reported via physician ratings, on a scale of 0 (most impact) to 7 (least impact)) was (Group-1/Group-2/Group-3, mean scores): patient ability to perform every-day tasks: 6.11/5.17/4.37, patient ability to interact fully with family and friends: 6.20/5.45/4.90, and patient ability to work/keep employment: 5.76/4.80/3.87. **CONCLUSIONS:** Over half of the SLE patients had an active disease while one-in-five were experiencing a flare in this study cohort, with significant variations observed within 5EU. Clinical and humanistic burden varied based on patient disease status, with highest burden observed among those experiencing flares.

SYSTEMIC DISORDERS/CONDITIONS – Health Care Use & Policy Studies

PSY98
ORPHAN DRUG POLICY: APPROACHES TO MARKET ACCESS IN MULTIPLE COUNTRIES
Shih DY, Jarrett J
MAPI, London, UK
OBJECTIVES: Despite increasing policy guidance to encourage the development of and access to orphan drugs, the policy landscape indicates a lack of transparency and consistency across countries. The objective of this study is to compare the orphan drug policies of Japan, South Korea, and Taiwan to the policies in the EU. **METHODS:** A targeted literature review was conducted to identify papers pertaining to orphan drugs in Japan, South Korea and Taiwan, with a focus on quantitative analysis for policy-making related to pricing and reimbursement from the payer perspective. No limits were placed on language. Country specific policy websites were hand-searched. **RESULTS:** A total of 3465 abstracts were identified for screening. Of those, 104 were eligible for full-text screening. The definition of prevalence with regard to rare diseases in Japan, South Korea and Taiwan was stricter than in the EU. All of them had introduced regulations, guidelines and incentives to the development of orphan-designated drugs. Strict HTA requirements were waived for rare diseases, although cost-effectiveness data are referenced in South Korea. In Japan and Taiwan, prices were reduced for existing drugs with new orphan-designated indications. Within the existing benefits of national health insurance schemes or under the coverage of rare disease regulations, full reimbursement was given, which is different from the partial reimbursements observed in certain European countries. In some cases, the application of drug treatment can be approved prior to or without market authorisation. The availability of orphan drugs to patients was not inferior to that of the EU. **CONCLUSIONS:** While access in Japan, South Korea and Taiwan is seemingly no different to the EU, there are no consistent or transparent policies in place in these countries. Policy makers should prepare innovative schemes that offer warranties to both payers and patients and establish a systematic evaluation procedure for manufacturers.

PSY99
MCDA APPROACH TO RANKING RARE DISEASES IN RUSSIA: PRELIMINARY RESULTS
Fedyaeva VK[1], Omelyanovsky VV[1], Rebrova O[2], Khan N[1], Petrovskaya EV[3]
[1]The Russian Presidential Academy of National Economy and Public Administration, Moscow, Russia, [2]Pirogov Russian National Research Medical University, Moscow, Russia, [3]Samara State Medical University, Samara, Russia
OBJECTIVES: The ranking and prioritization of rare diseases are crucial in order to define for which of them state support measures are justifiable. For this purpose the set of 16 criteria to assess rare diseases (8 related to the characteristics of disease, and 8 to the characteristics of treatment) was proposed by experts, so multi-criteria decision (MCDA) analysis approach could be useful. The aim of the study was to assess the reliability of the criteria set and to determine the relative importance of 16 criteria. **METHODS:** 85 experts were interviewed to estimate the importance of each criterion in the decision-making on financing MT for rare diseases. We used 10-point scale, where 10 points mean major importance to the priority indicator, and 1point means minor importance. Mean estimates were calculated using descriptive statistics, then means were normalized. **RESULTS:** Respondents were 41 years on average (ranging from 23 to 64 years), and included 20 public servants, 16 health administrators, 32 practitioners, and 14 researchers. 44 respondents had a scientific degree. The most important criteria were characteristics of treatment - “Effect of treatment on quality of life” and “Effect of treatment on life expectancy” with 1 points each. The least important criteria were both characteristics of the disease - “Cognitive disorders as manifestations of the disease and “Additional burden on the daily lives of care-givers” with 0.28 and 0.1 respectively. **CONCLUSIONS:** Characteristics of treatment turned out to be more important for respondents than characteristics of disease, therefore characteristics of treatment should be given consideration when evaluating rare diseases to determine priority financing.

PSY100
PATTERNS AND TRENDS IN OPIOID USE IN IRAN FROM 2007 TO 2011
Taheri F
Minitry of Health, Tehran, Iran
OBJECTIVES: Opioid analgesics are proven to be safe and effective in malignant or nonmalignant pains. The consumption trend of six opioids (Morphine, Codeine, Oxycodone, Fentanyl, Pethidine, and Methadone) in Islamic Republic of Iran assumed as an indicator for prescription pattern and is evaluated during five year period (2007-2011) as the aim of this study. **METHODS:** The data of opioid analgesic consumption were collected from FDO (Food and Drug Organization) of Iran. The collected data were converted to DDD (Define Daily Dose) for each of six selected opioids in order to be compared accurately. **RESULTS:** Overall consumption of opioids was grown during the period of investigation. Putting six selected opioids into two groups – synthetic and non-synthetic -, the growth rate of synthetic ones are obviously higher than those of non-synthetics. Opioid analgesics consumption in 2011 was shown to be 4 times more than the opioid consumption in 2007. The CAGR (Compound Average Growth Rate) between 2007-2011 were reported 111.27%, 33.11%, 16.48%, 3.91%, 3.76%, and -41.63% for Oxycodone, Methadone, Fentanyl, Morphine, Pethidine and Codeine respectively. The growth rate of mentioned above opioids for the last year of investigation was reported 41.12%, 16.54%, 29.99%, -0.38%, 7.66%, 23.67% respectively. **CONCLUSIONS:** Like other low consuming countries, consumption of opioid analgesics in Iran is limited by means of different kinds of barriers. There are also parameters which set a specific orientation in opioid consumption. Analyzing this trend, results in defining the barriers and other parameters clearly.

PSY101
ORPHAN DRUG APPROVALS IN EUROPE: HISTORICAL REVIEW AND TRENDS
Rodrigues J[1], Korchagina D[1], Rémuzat C[1], Brunet J[2], Tavella F[3]
[1]Creativ-Ceutical, Paris, France, [2]Assistance Publique des Hôpitaux de Marseille, Marseille, France, [3]Creativ-Ceutical, London, UK
OBJECTIVES: In Europe, orphan designation has been granted by European Medicines Agency since 2000. Molecules with orphan designation can benefit from a number of incentives to guarantee return on investment for manufacturers. Since introduction of orphan legislation, the number of Orphan Drugs (OD) has significantly increased. In 2012, total OD sales reached 13% of the whole pharmaceutical market. This study aims to analyse current situation and trends in OD approvals. **METHODS:** All ODs approved gaining marketing authorization was identified through EMA website. Extensions to a new disease were considered as an independent approval, while extensions of indication for the same condition were not considered. Information on drug status, indications, therapeutic area, and authorisation date was extracted. **RESULTS:** 77 orphan molecules were identified of which two have been withdrawn, and one orphan designation has expired. Yearly approvals continuously grow (from 2 ODs approved in 2002 to 12 and 8 drugs in 2012 and 2013 respectively). By mid-2014, already 6 were approved. There is a high imbalance within therapeutic area with 36% for oncology, 27% for endocrine, nutritional and metabolic disorders whereas the remaining 37% cover 11 therapeutic classes. No product has been approved for 7 therapeutic areas despite existence of rare disorders. Moreover, oncology is associated with the highest growth. **CONCLUSIONS:** Orphan drug market is rapidly growing but targeting selective therapeutic areas with high potential return on investment. The incentive policies happen to well function but discriminate among diseases. A review of orphan drug policies might be warranted to ensure patient equity in development of new OD.

PSY102
COMPARATIVE ANALYSIS OF HTA DECISIONS, PRICE AND REIMBURSEMENT LEVEL OF ORPHAN DRUGS IN FRANCE AND ITALY
Korchagina D[1], Tavella F[2], Rémuzat C[1], Kornfeld A[3], Toumi M[4]
[1]Creativ-Ceutical, Paris, France, [2]Creativ-Ceutical, London, UK, [3]Creativ Ceutical, Paris, France, [4]University of Marseille, Marseille, France
OBJECTIVES: While there exist a number of incentives to stimulate research and development of orphan drugs (OD), the Health Technology Assessment (HTA) agencies do not offer specific path for OD in most countries where it is left to payer value judgement. This leads to a high inequity in patient access to OD. The study aims at comparing the HTA decisions, price and reimbursement level of OD in France and Italy. **METHODS:** All OD assessed since 2000 were analysed. Prices, reimbursement rates and decision details were extracted for each drug using Farmadati Italia database for Italy and Transparency committee reports, AMELI’s national health insurance and Thériaque databases for France. **RESULTS:** Among 74 OD approved in Europe 66 are available in Italy compared to 53 in France. All ODs available in France are officially available in Italy. The average delay between the market authorization and the price and reimbursement decision was about 16 and 17 months in France and Italy, respectively. In France all available drugs are 100% reimbursed through hospital, 36 molecules are available in retail pharmacy with reimbursement from