OBJECTIVES: The current analysis evaluates the long-term impacts on household productivity and social participation of CZP 400mg Q4W combination and monotherapy over 5 years. **METHODS:** In this open-label extension (OLE) (NCT00160693) patients (pts) originally enrolled in FAST4WARD (NCT00548834) or study 014 (NCT00544154) received CZP 400 mg Q4W for 24 wks. Pts who completed or withdrew on/after Wk12 in either study were eligible and were permitted to take DMARDs in OLE. Household productivity and social participation were assessed through the RA-specific Work Productivity Survey (WPS-RA); results are reported up to Wk268 (5.2yrs). The analyzed population consisted of (1) Wk 24 CZP completers from FAST4WARD (N=75) or 014 (N=96) who entered the OLE (all pts group) and (2) FAST4WARD CZP completers who entered OLE and did not receive MTX/DMARDs (N=48) (monotherapy subgroup). **RESULTS:** In both populations analyzed, a rapid reduction in the number of days of household work days missed per month was seen from feeder study baseline (BL, 7.4 and 11.1 mean days respectively) over 24wks of the feeder studies to OLE entry (3.5 and 4.1 mean days respectively) and continued to decline over time, up to Week 268 (1.2 and 1.4 mean days respectively). Increased participation in family/social/leisure activities was reported in both populations, with a decrease in the number of days missed per month from feeder study baseline (4.4 and 6.2 mean days, respectively), to entry to OLE, at a mean of 1.3 and 1.1 days respectively for monotherapy pts; improvements continued over the 5 years to 0.4 and 0.2 days on average in the 2 populations respectively. **CONCLUSIONS:** CZP treatment, in combination with MTX/DMARDs or as monotherapy, rapidly decreased the number of household work or social/family/leisure days missed per month. These improvements were maintained up to 5 years with open-label CZP following 24 wks double-blind CZP therapy.

MUSCULAR-SKELETAL DISORDERS - Health Care Use & Policy Studies

PMS68

THE USE OF MONITORING SYSTEMS TO BETTER REGULATE DRUG CONSUMPTION IN HUNGARIAN HOSPITALS

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OBJECTIVES: Due to the global economic crisis, most of the actions of the Hungarian government are focused on cost reductions, including in the health care sector. According to the ownership structure's changes (i.e., the state becoming the owner), the most important thing is to create a well-monitored and centralized hospital system. In addition to these changes, the government seeks to centralize the procurement of pharmaceuticals and medical equipment at state-owned hospitals. **METHODS:** We have prepared literature review and interviews with high level hospital and political leaders to find how can we strengthen the regulation of drug consumption at hospitals, which is at this time without strict controls. **RESULTS:** Due to the specific objectives of the HunDRG system, which are focused more on monitoring the number of DRG cases than tracking resources, there are no incentives for hospitals to maintain strict inventories of their drugs. Except for biological drugs, which use an itemized financing system, there is no pressure by the government to monitor the medical costs at the unit level; as such, only hospital data exists. Based on IMS data in 2011, the total hospital sector was valued at approximately 100 billion HUF. Most of the hospitals do not have adequate computer systems to monitor the patient-level data. **CONCLUSIONS:** In conclusion, the so called unit-dose system could be a good solution to measure the drug consumption at the patient level and to improve drug security (trial system). To sum up, it is very important to gain more data regarding the Hungarian hospital system to be able to create a sustainable, transparent, highly-regulated, and centralized public health care system.

PMS69

KEY DRIVERS FOR PRICING AND REIMBURSEMENT FOR BIOLOGIC DRUGS IN FRANCE

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OBJECTIVES: In France, the reimbursement decisions and price negotiations for new drugs are highly influenced by the National Authority of Health (HAS) recommendations communicated in the formal health technology assessment (HTA). This study aimed to analyse past criterions and consider future possible requirements influencing future submissions. **METHODS:** A convenient internet literature review was conducted to identify categories for value drivers in the evaluation of the incremental medical benefit (ASMR) for a new product. An analysis of five biological products reviewed 2006-2012 for rheumatology disorders was conducted using these criterions. Based on the findings, exploratory interviews with two ex-HAS members were performed to gain insight into future potential evidence requirements. **RESULTS:** From the literature review three categories of evidence were developed. Firstly 'socioeconomics', to include the French payers' perspective of burden and cost of illness. The second category was 'clinical evidence', evaluating the added therapeutic value for a target population, the clinical efficacy and safety. The third category was 'real world data', to establish effectiveness and long-term safety post-launch. From the analysis it was demonstrated that only products targeting patients with an insufficient response to anti-TNFs were recommended a high -level II- ASMR. Only 2 of 14 phase III studies used an active comparator in Phase III superiority studies. Open label extension studies were commonly used to provide post-launch data. Findings of the interviews suggested that in the future superiority verses current standard of care in France for a clear target population would be the expectation for an ASMR ≤ IV from the HAS. **CONCLUSIONS:** These findings emphasise the need to integrate payer evidence requirements into the clinical development strategy early on. Effort should be directed towards the identification of a clear target population demonstrating superior efficacy to standard of care.

PMS70

UTILIZATION OF PAIN MEDICATIONS AMONG OSTEOARTHRITIS PATIENTS WHO INITIATED DULOXETINE AND STANDARD OF CARE FOR PAIN MANAGEMENT

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OBJECTIVES: To compare utilization of pain medications between osteoarthritis (OA) patients initiating duloxetine and standard of care (SOC) after duloxetine's approval for OA. **METHODS:** Pharmacy and medical claims from SDI Health were analyzed for adult osteoarthritis patients (ICD-9-CM: 715.xx) initiating duloxetine or SOC (celecoxib, gabapentin, pregabalin, or venlafaxine) between 11/2010 and 4/2011. Treatment initiation was defined as no pill coverage over 90 days prior, and first dispense date was defined as index date. Included patients did not use opioids in 90 days before index date. Propensity score matching was used to select patients with similar baseline demographic and clinical characteristics for duloxetine and SOC cohorts. Compliance to index medication was assessed via medication possession ratio (MPR), proportion of days covered (PDC) and proportion discontinued (a 60+-day gap in medication access) for 6 months after index date. Opioids use after index date was assessed and regression models were estimated to compare opioid use between cohorts. **RESULTS:** A total of 1102 patients initiated duloxetine and 4,302 patients initiated SOC. After matching, 1,021 patients were selected for duloxetine (mean age: 63 years; female: 79%) and SOC (mean age: 64 years; female: 79%) cohorts, respectively. Duloxetine cohort had significantly higher MPR (0.80 vs. 0.74) and PDC (0.52 vs. 0.43), and were less likely to discontinue initiated medication (55% vs. 68%) than SOC cohort (all $p<0.001$). Duloxetine cohort was less likely to use opioids after index date (49% vs. 56%, $p=0.002$), and had fewer days on opioids (mean: 18 vs. 22, $p=0.004$) than SOC cohort. After adjusting for baseline characteristics, duloxetine cohort initiated opioids later than SOC cohort (Hazard ratio: 0.85, 95% confidence interval: 0.75-0.97) and had fewer days on opioids (beta: -4.0, $p=0.011$). **CONCLUSIONS:** Patients with OA initiating duloxetine were associated with better compliance to initiated medication and less likely to use opioids than those initiating SOC.

PMS71

UTILIZATION OF DULOXETINE AND CELECOXIB IN OSTEOARTHRITIS PATIENTS

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OBJECTIVES: To describe utilization patterns of duloxetine and celecoxib and subsequent opioid use among patients with osteoarthritis (OA) after duloxetine's approval for OA. **METHODS:** Pharmacy and medical claims from SDI Health were analyzed for adult osteoarthritis patients (ICD-9-CM: 715.xx) who initiated duloxetine or celecoxib between 11/2010 and 4/2011. Initiation was defined as no pill coverage in 90 days prior. Included patients had continuous enrollment in 6 months before and after the initiation and did not use opioid in 90 days before the initiation. Propensity score matching was used to select patients with similar demographic and clinical characteristics for duloxetine and celecoxib cohorts. Compliance to index medication was assessed via medication possession ratio (MPR), proportion of days covered (PDC), and proportion discontinued (no access for 60 days). Initiating dose and opioid use after index date was assessed. Cox proportional hazard model was estimated to compare time to first opioid use. **RESULTS:** A total of 1360 patients initiated duloxetine and 1,408 patients initiated celecoxib. After matching, 784 patients were selected for duloxetine (mean age: 66, female: 78%) and celecoxib (mean age: 66; female: 76%) cohorts, respectively. 92.5% of duloxetine cohort started on ≤60mg/day, the recommended dose, and 72.8% of celecoxib cohort started on ≤200mg/day. Duloxetine cohort had higher MPR and PDC and a lower proportion of discontinuation than celecoxib cohort (MPR: 0.81 vs. 0.70; PDC: 0.51 vs. 0.35; discontinuation: 57% vs. 78%. all $p<0.001$). A lower proportion of duloxetine cohort used opioids after index date (48.6% vs. 68.5%, $p<0.001$), and started on opioid later than celecoxib cohort (mean: 132 vs. 107, $p<0.001$). After controlling for baseline characteristics, duloxetine cohort initiated opioids later than celecoxib cohort (Hazard ratio: 0.67, 95% confidence interval: 0.58-0.76). **CONCLUSIONS:** OA patients initiating duloxetine had better compliance and a lower likelihood of opioid utilization than those initiating celecoxib.

PMS72

ADHERENCE AND CHANGE OF OPIOID USE AFTER INITIATING DULOXETINE OR CELECOXIB AMONG PATIENTS WITH OSTEOARTHRITIS

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OBJECTIVES: Opioids are commonly used to manage chronic pain, including osteoarthritis (OA). Duloxetine is approved for OA therapy, but no study has assessed changes in utilization of opioid therapy following its approval. This study assessed adherence and the change of opioid use between OA patients who initiated duloxetine versus celecoxib. **METHODS:** Employing administrative claims data, OA patients aged 18+ years who initiated duloxetine or celecoxib between November 2010 and April 2011, and used opioids in 6 months before the initiation, were identified. Initiation was defined as no access to the same medication over the prior 90 days, and the first dispense date of index medication was denoted as the "index date". Patients with >80% days covered by index medication during follow-up were