

academic productivity, social behaviour), which are not considered as serious from a regulatory perspective, but may have important consequences for patients.

**Objectives:** 1) To determine the frequency and types of ADRs with social impact in the CVP database; 2) To evaluate trend over time in the number of ADRs with social impact; 3) To identify drugs most frequently associated with ADRs with social impact.

**Methods:** Descriptive study including ADRs reported by healthcare professionals or consumers until September 30th 2016 and collected in CVP online database. MedDRA preferred terms (MPTs) associated with social impact were identified independently by two experts. Heterogeneity of ADRs with social impact according to patient age and sex, suspected drug class (ATC classification), and reporter type was assessed.

**Results:** A total of 41 MPTs associated with social impact were found, yielding 11,005 cases in the CVP database, out of which 8,910 (81.0%) were reported as serious. Most frequent events were lifestyle issues (3,272, 29.7%), personality disorders (2,903, 26.4%), neurological disorders (2,391, 21.7%) and mental impairment (1,761, 16.0%). Number of ADRs with social impact increased over time, with a peak in 2009 (746 cases) and in 2015 (1,654 cases). Most common suspected drugs were nervous system drugs (4,811 cases, 43.7%) and antineoplastic and immunomodulating agents (2,452, 22.3%). Females accounted for 54.1% for the cases and the majority were in the age 18-65 (62.0%), which is very similar to the distribution of all other types of ADRs in CVP. However, compared to other types of ADRs, a lower proportion was reported by health professionals (54.2% vs. 65.1%).

**Conclusions:** Serious ADRs with social impact represent an important proportion of the identified cases. It may be important to include a code that indicates a social impact either as MedDRA terms or in the CVP reports.

### 643. Adverse Drug Reactions to Thalidomide in Hansen's Disease Patients

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**Background:** In Brazil, thalidomide (TLD) is the first-line treatment for Erythema Nodosum Leprosum (ENL) in patients with Hansen's disease. The lack of information concerning adverse drug reactions (ADR) related to TLD and the incipient surveillance has motivated this study.

**Objectives:** To estimate the frequency of ADR associated with TLD use in patients with ENL. In addition, issues related to prescription, dispensing and pharmacovigilance activities of TLD were evaluated.

**Methods:** Cross-sectional study involving patients attending dermatologic clinics of a public referral hospital for infectious diseases in Minas Gerais State, Brazil. All patients ( $\geq 18$  years) using TLD for ENL between July and October 2016 were invited to participate in the study. Patients were interviewed and asked to respond to questions about socio-demographic variables, variables related to their health state, understanding of TLD treatment, accordance with national regulatory law, and ADR experienced during the treatment.

**Results:** A total of 110 patients were interviewed. Most were men (65.5%) aged on average 47.8 years old. The mean length of TLD use was 37.3 months. Twenty-three out of 38 women reported the use of injectable medroxyprogesterone, 16.7% had been submitted to a previous sterilization procedure, 19.4% were not in fertile age, and 33.7% of patients referred condom use. Approximately 80.0% of the patients knew they used TLD for ENL or Hansen's disease whereas 19.3% were not aware about the reason of TLD's use. Most ADR comprised dry skin (94.6%), paresthesia (82.7%), somnolence (77.3%), weight gain (66.4%), tremor (60.9%), adynamia (60.0%), pain (52.7%), dry mouth (52.7%), anxiety (52.7%), impotence (25.5%), lower limb edema (20.9%) and thrombosis (6.4%).

**Conclusions:** ADR were very common among TLD patients. Women in fertile age are under contraceptive use to ensure birth control, but not all patients reported the use of condom. Apparently, most patients understand the need of TLD and perceive the main adverse effects.