**ORPHAN DRUG MARKET ANALYSIS IN TURKEY**

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**Background:** Rare diseases are defined as life-threatening, deteriorating or serious chronic conditions affecting a relatively small number of patients. Orphan drugs, specifically designed for treatment of rare diseases are of special importance in all healthcare systems. Drugs approved for an orphan indication in EMA, also play significant role in the Turkish pharmaceutical market.

**Objective:** The purpose of this study is to analyze the orphan drug market in Turkey and to identify its share in pharmaceutical expenditures.

**Methods:** The study was undertaken from the Turkish health care payer perspective (SSI). An Excel sheet was formed to calculate the ratios and results. Resource utilization data were obtained from Orphanet Report April 2016, RxMediapharma, Social Security Institution Health Implementation Guideline Annex 4/A and Annex 4/C.

**Results:** 45 products, reimbursed by SSI in the Turkish Market, constituting 52% of 86 products are classified as “Orphan Drug” by the EMA**.** There are 15 products, as orphan drug, with marketing authorization and in the positive list (Annex 4/A) that constitute 33% of overall orphan drug market. Likewise, products with orphan drug status, supplied through Turkish Pharmacists’ Association channel on NPP basis and in the overseas product list (Annex 4/C) comprise 67% of total orphan drug market. The top 3 Companies with orphan drug investment are; Novartis, Celgene and Shire. In 2015, 5 orphan drugs entered the market with reimbursement approval in Antineoplastic and Immunomodulating, Respiratory, Musculo-skeletal System, Alimentary Tract and Metabolism, Cardiovascular System ATC groups.

**Conclusion:** The total expenditure of orphan drugs in 2015 was €208,868,926 (664.203.185 TL). Orphan Drugs had a share of %4,2 in the global pharmaceutical budget.