

<b>Meeting / Value in Health Info:</b>	ISPOR 12th Annual European Congress Paris, France October, 2009
<b>Code:</b>	PMH8
<b>Disease:</b>	Mental Health, Depression
<b>Topic:</b>	Clinical Outcomes Studies (COS)
<b>Topic Subcategory:</b>	EE
<b>Title:</b>	CLINICAL EFFICACY AND SAFETY OF DULOXETINE IN COMPARISON WITH PLACEBO IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER IN POLAND
<b>Author(s):</b>	Pankiewicz O1, Jagodzinska K1, Rys P1, Lach K1, Jarczewska D1, Cel M2, Mierzejewski P2, Bartminski W3, Plisko R1, Wladysiuk M11HTA Consulting, Krakow, Poland, 2Eli Lilly, Warsaw, Poland, 3Eli Lilly, Windlesham, Surrey, United Kingdom

**OBJECTIVES:**The objective of this analysis was to compare efficacy and safety of duloxetine with placebo in the treatment of major depressive disorder in Poland.

**METHODS:** Comparison was based on a systematic review, carried out according to guidelines published by the Cochrane Collaboration and the Agency for Health Technology Assessment in Poland. The most important medical databases (MEDLINE, EMBASE, CENTRAL) were searched. Two reviewers independently had selected trials, assessed their quality and extracted data. For efficacy analysis improvements in Hamilton Rating Scale for Depression (HAM-D) and quality of life were measured. Percentage of patients responding to treatment (defined as = 50% improvement in HAM-D) and percentage of patients achieving total remission (defined as = 7 points HAM-D-17) were also reported. Head-to-head comparisons based on randomized controlled trials (RCTs) were performed both for safety and efficacy analysis.

**RESULTS:**The results of 14 RCTs were included in the analysis. After 7 to 9 weeks of treatment duloxetine allowed better improvement than placebo in HAM-D scores (WMD = -2.26 [-2.94; -1.57]) and in quality of life (WMD = -3.60 [-4.89; -2.31]). Percentage of patients with response to treatment (RB=1.42 [1.29; 1.56]), NNT=6.95 [5.53; 9.37]), and with total remission (RB = 1.45 [1.29; 1.64]), NNT=8.92 [6.80; 12.93]) was also statistically significantly higher for duloxetine group. Although risk of adverse events was significantly higher in duloxetine treated patients (RR=1.19 [1.13; 1.24]; NNH=8.60 [6.75; 11.84]), no differences in the incidence of serious adverse events were observed (RR=0.95 [0.49; 1.84]). Withdrawals due to adverse events were significantly more frequent in duloxetine group than in placebo group (RR=2.11 [1.61; 2.77], NNH=17.31 [12.87 26.44]).

**CONCLUSION:** Duloxetine is efficacious drug in the treatment of patients with major depressive disorder. Safety profile seems to be acceptable (slightly worse than placebo).