

# ABSTRACT

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Title of Diploma Thesis: Pharmacovigilance of active substance zolpidem

**Introduction:** Drug safety became very important topic in the second half of 20th century, even beyond pharmacy. It relates to increasing impact on testing of drugs before launch onto the market, but also following monitoring, so the benefit and risk ratio of drug can be determined. Pharmacovigilance takes care of monitoring of drug use risk. Zolpidem is active substance from class hypnotics and it is used for short-term treatment of insomnia. Most professionals recommend zolpidem as first line treatment of acute insomnia. That is why it can be considered as one of the most important hypnotic drugs.

**Objectives:** The aim of this diploma thesis is to analyze spontaneous reports for adverse drug reaction for zolpidem from years 2004 to 2017. The thesis focus on reports from the Czech republic but also from the whole world. The information in SPC of medicinal products containing zolpidem which were distributed from 2004 to 2017 are compared.

**Methods:** Following data from years 2004 to 2017 were used: 1) List of spontaneous reports for adverse reaction from the Czech republic (source: SÚKL) 2) List of spontaneous reports for adverse reaction from the whole world (source: EMA) 3) List of medicinal products distribution in the Czech republic (source: SÚKL) 4) SPC of medicinal products containing zolpidem distributed in the Czech republic.

**Results and conclusion:** Use of zolpidem in the Czech republic was increasing from year 2004 to 2017. 53, 6 % of DDD of zolpidem were distributed in big 100 tablet packages in 2017, which leads to suspicion that the big packages can be misused. Number of report for zolpidem was increasing. The reason is increase of use of zolpidem and general increase of all reports. There was no other suspicious or interacting drug reported along with zolpidem in 68 % reports. 89 % of reports were serious. More than half of patients from reports were

women. Patients from report were from all ages categories. Almost half of reports were from doctors, almost quarter from pharmacists, the rest were from patients and other medical staff members. Number of reports for zolpidem in the world also increase. Same categories of adverse drug reactions are reported in both world and the Czech republic.