P-1108 - SAFETY DATA ON SECOND-GENERATION ANTIPSYCHOTICS: CHANGES FROM LICENSING TO POSTMARKETING

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Background: During drug development pharmaceutical manufacturers conduct numerous clinical trials to demonstrate therapeutic efficacy and safety of new antipsychotic drug candidates. However, clinical trials are impacted by the need to comply with scientific standards and regulatory requirements for approval. While supplying information necessary for approval, these trials provide data on a limited sample, obtained under conditions often removed from clinical practice. Drug labeling containing warnings, precautions and adverse events undergo regular revision once the population-based application provides evidence for need to change the information on the safety profiles of drugs.
Aims: To provide a systematic review of the safety profiles of 9 selected second-generation antipsychotic agents including aripiprazole, asenapine, iloperidone, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, ziprasidone upon and following FDA approval.
Methods: To gain access to safety profiles of the selected antipsychotic drugs we investigated the FDA's Summary Basis of Approval Documents. Comparison of safety profiles was made possible via the revisions provided in MedWatch Database.
Results: Safety data available upon approval fail to provide a full range of emerging side effects. Our results indicate that the labeling of all investigated antipsychotic drugs has been substantially expanded due to safety reasons both with regard to inclusion of adverse reactions (ARs) newly detected in the postmarketing phase and to providing more precise estimates for the incidence of individual ARs already described at the licensing phase.
Conclusions: Population-based application reveals unforeseeable health risks and additional costs both on manufacturer and patient level, emphasizing the need for novel methods for initial safety evaluation.

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