Abstract/ Study results

Title
ABILIFY® for the Adolescent Bipolar I Mania Indication Tool Effectiveness Evaluation Survey

Keywords
ABILIFY, aripiprazole, risk minimisation, effectiveness, evaluation

Rationale and background
ABILIFY (aripiprazole) is indicated for the treatment of moderate-to-severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older. Otsuka implemented a risk management plan (RMP) with two Risk Minimisation (RM) communication tools; an HCP (healthcare professional) FAQ brochure and a Patient/Caregiver information brochure (PCIB). Following PRAC (EMA Pharmacovigilance Risk Assessment Committee) approval of centrally-developed materials, country-level adaptation distribution was agreed between local representatives of the MAH and local competent authorities. This resulted in wide variation in target audiences, numbers receiving the RM tools, and tool format.

Research question and objectives
The aims of this study were to evaluate the effectiveness of the ABILIFY RM tools and to establish baseline levels of tool usage, knowledge and behaviours of HCPs and patients/ caregiver.

Study design
This was a non-interventional, cross-sectional study comprising web-based HCP and Patient/Caregiver surveys. The study was conducted in 10 EU member states, and data collection occurred in two stages; between 27th July 2014 and 9th July 2015 and between 10th July 2015 and 4th January 2016.

Subjects and study size, including dropouts
Study population comprised HCPs, Patients and Caregivers involved in treatment of moderate-to-severe manic episodes in adolescents with Bipolar I Disorder with ABILIFY. In total, 23,282 initial invitations were issued to HCPs. Patient and Caregiver recruitment occurred via HCPs. The total numbers of participants included 118 HCPs, 10 Patients and six Caregivers.

Variables and data sources
HCP and Patient surveys comprised primarily multiple-choice questions, with conditional branching and optional descriptive comments in a small number of sections.

Results

HCP survey

Awareness of the RM tools was limited among HCPs. HCPs who reported treating a greater number of patients with ABILIFY, however, were more likely to be aware of the tools. Furthermore, correct responses to case study questions were not consistently, positively correlated to HCPs having received the tools. This may indicate that questions were answered based on pre-existing clinical knowledge.

With approximately half of HCP respondents answering correctly, this may also be suggestive of some degree of guesswork; however, it was not possible to assess this formally. Moreover, the results suggest that HCPs with more experience with ABILIFY were more likely to distribute PCIBs to Patients/Caregivers and that distribution occurred mostly on the first visit to the HCP.

Patient and Caregiver survey

Of those who received the PCIB, the majority of patients and all caregivers reported having read the tool, in whole or in part, once; however, no respondents reported having read the PCIB more than once. The majority of patients, who had read/referred to the PCIB, monitored their weight while on ABILIFY and demonstrated positive behaviour as to notifying their HCPs of potential adverse drug reactions and pre-existing conditions. None of the patients or caregivers indicated that they would cease treatment on their own, without seeking advice.

Conclusions

ABILIFY RM tools were widely and comprehensively distributed; however, study results showed that the tools displayed limited utility and effectiveness as to HCP and Patient awareness and education.

The MAH concluded that the RM tools should be discontinued.