



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2015
EMA/PRAC/194999/2015
Pharmacovigilance Risk Assessment Committee

PRAC recommendations on signals for update of the product information

Adopted at the 9-12 March 2015 PRAC

Aripiprazole – Aggression and related events (EPITT no 18127)

Having considered the available evidence in the literature and from individual case safety reports, the PRAC has agreed that the MAH(s) of aripiprazole-containing medicinal products should submit a variation within 2 months, to amend the product information as described below (new text underlined).

Summary of Product Characteristics:

Section 4.8 – Undesirable effects:

Tabulated list of adverse reactions

Psychiatric disorders

Frequency 'not known': aggression

Package Leaflet:

Section 4: Possible side effects

The following side effects have been reported since the marketing of oral aripiprazole but the frequency for them to occur is not known: Aggression

The PRAC has further agreed that the MAH for Abilify and Abilify Maintena should submit in the next PSUR (data lock point 16/07/2015), a cumulative review of aripiprazole overdose and the risk of aggression and related events.

