

## Update of the PIL and SmPC and respective variation for Aripiprazole

### Aripiprazole

is an antipsychotic medicine that is used to treat the symptoms of psychotic conditions such as schizophrenia and bipolar I disorder (manic depression) sold under the brand name of Abilify.

On 27th February 2020 The Committee for Medicinal Products for Human Use (CHMP) adopted a variation to the Marketing Authorisations for Abilify. The CHMP adopted the following conclusions:

**Update of section 4.8 of the SPC to add the adverse reaction “photophobia” with the frequency “Uncommon”, under SOC eye disorders. The package leaflet is updated accordingly.**

### European procedures

The applications do not require supporting information and will be accepted by Member States Competent Authorities without further assessment or amendment. The RMS will take responsibility for the assessment of the implementation of the final SmPC and PIL texts. National translations of the product information should be submitted with your Type IB variation.

### Deadline

**29th May 2020**

### How ELC can help you

- Update Product Information (SPC and PIL)
- Variation type IB with impact on Product information package compilation
- eCTD publishing
- Translation if required

ELC Group provides a full range of support and advice for any third-party arrangements to be entered into by MAHs, and can help ensure full compliance across intergrated pharmacovigilance activities.



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