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CLINICAL DEVELOPMENT OF ANTIDEPRESSIVE DRUGS - THE VIEWPOINT OF THE INDUSTRY

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The clinical development program strategy of a new treatment of depression to be registered in Europe must be built in agreement with recommendations of the CHMP guidance.
Demonstration that an antidepressant is effective in treatment of major depressive disorders requires consideration of specific recommendations notably regarding the use of placebo and reference drugs, efficacy assessment, designs features and safety aspects.
In the field of depression, comparisons between test medicinal product and reference drugs are difficult to interpretate since the level of placebo response is high and variable. An adequate evaluation of antidepressant efficacy is firstly based on randomised double blind comparison versus placebo. For short term efficacy, studies with 6 week-treatment period are required and three arm trials including placebo and active control are recommended. Regarding the long term efficacy, relapse prevention study is the design recommended for demonstrating that the short term effect can be maintained over time.
Assessment of efficacy criteria includes both clinical relevance and statisitical significance, particularly:
Improvement expressed as difference between baseline and post-treatment score in symptomatology and as proportion of responders.
Remission, defined as a condition where no or only few signs remained, with a justified cut-off on a validated rating-scale.
In randomised withdrawal trials, efficacy is expressed as number of patients relapsing and/or time to relapse.
The acceptable scales for use as primary endpoint include the HAM-D17 scale, the MADRS scale. Cautions regarding designs features, safety assessment and the global methodological issues faced in conducting such program will be detailed in the presentation.

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