HealthManagement
Promoting Management and Leadership

Volume 1 - Issue 1, November-December 2007 - Exhibitors @ RSNA 2010

Sanofi-Aventis Announces Approval of Labelling Update of Acomplia® in Europe

Sanofi-Aventis announced that the Committee for Medicinal Products for Human Use (CHMP), after re-evaluation, confirms the positive benefit-risk profile of rimonabant in the indicated patient population and has issued a positive opinion on the labelling update.
Acomplia® labelling has been updated based on data reflecting one year of post-marketing experience mainly from Germany, France and the UK, as well as results of five additional clinical trials completed since the original dossier was approved.
With this updated labelling, Acomplia® is now contraindicated in patients with ongoing major depressive illness and/or ongoing anti-depressive treatment. “Special Warnings and Precautions” of the Summary of Product Characteristics (SmPC) have been updated as well to include information on depressive disorders.

Published on : Thu, 1 Nov 2007