



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 15-18 October 2012

Name of medicine	INN	Marketing authorisation holder	Scope
Abilify	aripiprazole	Otsuka Pharmaceutical Europe Ltd.	CHMP opinion recommending to update sections 4.4 and 4.8 of the SmPC to include pathological gambling as a new post-marketing adverse reaction and to add a warning that patients with a prior history of pathological gambling may be at increased risk and should be monitored carefully.
Ketek	telithromycin	Aventis Pharma S.A.	CHMP opinion recommending to update section 4.3 of the SmPC to contraindicate the concomitant administration of telithromycin and colchicine in patients with renal and/or hepatic impairment.
Sutent	sunitinib	Pfizer Ltd.	CHMP opinion recommending to update sections 4.4 and 4.8 of the SmPC further to a review of cases of erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis conducted at the request of the CHMP.

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Tysabri	natalizumab	Elan Pharma International Ltd.	CHMP opinion recommending to update section 4.4 of the SmPC to include a new recommendation for re-testing every 6 months anti-JCV antibody negative patients.