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Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 18-21 March 2013

Name of medicine	INN	Marketing authorisation holder	Scope
Incivo	telaprevir	Janssen-Cilag International N V	CHMP opinion to update sections 4.4 and 4.8 of the SmPC with information on reported toxic epidermal necrolysis (TEN) cases. The package leaflet is updated accordingly. The CHMP endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.
Mabthera	rituximab	Roche Registration Ltd	CHMP opinion to update section 4.4 of the SmPC to include the occurrence of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) in patients receiving MabThera for oncology and autoimmune indications, and to update section 4.8 to include SJS and TEN with the frequency 'very rare' in patients receiving MabThera for rheumatoid arthritis. The package leaflet

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			is updated accordingly. The CHMP endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.
Sutent	sunitinib	Pfizer Limited	CHMP opinion to add a new warning in section 4.4 and to update section 4.8 of the SmPC with regards to cholecystitis, following a cumulative review conducted at the request of the PRAC in a signal recommendation.
Velcade	bortezomib	Janssen-Cilag International N V	CHMP opinion to add a new warning in section 4.4 of the SmPC on very rare cases with unknown causality of John Cunningham (JC) virus infection resulting in progressive multifocal leukoencephalopathy (PML) and death reported in patients treated with Velcade.
Victrelis	boceprevir	Merck Sharp & Dohme Ltd.	CHMP opinion to update section 4.4 of the SmPC with information on hypersensitivity reactions, and addition of the adverse events angioedema and drug rash with eosinophilia and systemic symptoms (DRESS) to section 4.8. These updates were based on the identification of new post-marketing signals. The Package Leaflet is updated accordingly.
Zometa	zoledronic acid	Novartis Europharm Ltd.	CHMP opinion to update section 4.5 of the SmPC to add additional information on concomitant treatment with anti-angiogenic medicinal products. Furthermore sections 4.4 and 4.8 of the SmPC are updated with information on cardiac arrhythmia, seizures, numbness and tetany as secondary events related to hypocalcaemia with the frequency 'very rare'. The package leaflet is updated accordingly.

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Leganto Neupro	rotigotine	UCB Manufacturing Ireland Ltd.	CHMP opinion to update sections 4.4 and 4.8 of the SmPC to include angioedema, tongue oedema and lip oedema as adverse reactions with unknown frequency as well as disorientation as an uncommon adverse reaction and to amend the warning on hallucinations with a broader warning on abnormal thinking and behaviour. This information is included following assessment of PSUR data. The package leaflet is updated accordingly.