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Press office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 25-28 April 2016

Name of medicine	INN	Scope
Adcetris	bretuximab vedotin	CHMP opinion to include warnings in section 4.4 on important potential risks of hepatotoxicity, gastro-intestinal complications and pulmonary toxicity. The package leaflet is updated accordingly.
Aprovel, Karvea, Irbesartan Zentiva	irbesartan	PSUR assessment resulting in a variation to update section 4.8 of the SmPC with the adverse reaction "thrombocytopenia" with frequency 'not known'. The package leaflet is updated accordingly.
Cubicin	daptomycin	PSUR assessment resulting in a variation to update section 4.8 of the SmPC with the adverse reaction "acute generalized exanthematous pustulosis", with frequency 'not known'. The package leaflet is updated accordingly.
Lemtrada	alemtuzumab	PSUR assessment resulting in a variation to update of section 4.4 of the SmPC to include a warning on the risk of "listeriosis/listeria" and "bradycardia". The package leaflet is updated accordingly.

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Name of medicine	INN	Scope
Otezla	apremilast	PSUR assessment resulting in a variation to update of section 4.8 of the SmPC to add “gastrointestinal haemorrhage”. The package leaflet is updated accordingly.
Privigen	human normal immunoglobulin	CHMP opinion on Type II variation to update the safety information particularly to amend the existing information on haemolysis and to include Transfusion-related acute lung injury (TRALI).The package leaflet is updated accordingly.
Reyataz	atazanavir	CHMP opinion on Type II variation (to extend the indication to paediatric patients aged 6 to less than 18 years infected with HIV-1 strains resistant to multiple protease inhibitors) which includes updating section 4.8 of the SmPC with reference to elevation in ALT levels, which were more frequently reported in paediatric patients than in adults. The package leaflet is updated accordingly.
Zoledronic acid	zoledronic acid	PSUR assessment resulting in a variation to update of section 4.8 of the SmPC to add “acquired Fanconi syndrome” as adverse reaction with the frequency ‘rare’. The package leaflet is updated accordingly.