



4 April 2016
EMA/76590/2016
Press office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 29 March – 1 April 2016

Name of medicine	INN	Scope
Glustin, Actos, Competact, Tandemact, Glubrava	pioglitazone, pioglitazone/metformin, pioglitazone/glimepiride, pioglitazone/alogliptin	PSUR assessment resulting in a variation to update sections 4.4 and 4.8 of the SmPC with epidemiological data from the post-marketing experience regarding an increased risk of fractures in both men and women and caution is advised in patients with long term treatment. The package leaflet is updated accordingly.
Constella	linaclotide	PSUR assessment resulting in a variation to update the product information to include “lower gastrointestinal haemorrhage including haemorrhoidal haemorrhage and rectal haemorrhage” in sections 4.4 and 4.8 of the SmPC. “Nausea” and “vomiting” were also added to section 4.8. The package leaflet was updated accordingly.



Name of medicine	INN	Scope
Zeffix	lamivudine	PSUR assessment resulting in a variation to update SmPC section 4.2 for a switch to or addition of an alternative agent without cross-resistance to lamivudine based on therapeutic guidelines. Subsequent changes were deemed necessary in sections 4.4 and 5.1 of the SmPC to support this information. To update the product information in accordance with the latest QRD v10 template.
Neuraceq	18F-florbetaben	During the PSUR assessment the section 4.8 the SmPC was updated to qualify "injection/application site erythema" with a frequency 'common' and to update the number of administrations of the product with regards to the overall safety information. The package leaflet is updated accordingly.
Imnovid	pomalidomide	PSUR assessment resulting in a variation to update sections 4.4 and 4.8 of the SmPC to add a warning on non-melanoma skin cancer, on reactivation of hepatitis B, to add the adverse reactions gastrointestinal haemorrhage with a frequency 'common', haemorrhagic disorder in the description of selected adverse reactions, basal cell carcinoma and squamous cell carcinoma of the skin with a frequency 'uncommon', hepatitis B reactivation with a frequency 'unknown', herpes zoster re-activation with a frequency 'common' and to broaden the preferred term pneumonia to "pneumonia (bacterial, viral and fungal infections, including opportunistic infections)".
Tafinlar	dabrafenib	CHMP opinion to update section 4.8 of the SmPC to add "bradycardia" and "heart rate decreased" as known adverse events of dabrafenib use in combination with trametinib.
Xalkori	crizotinib	PSUR assessment resulting in a variation to update sections 4.2, 4.4 and 4.8 of the SmPC to reinforce information on adverse reactions which may result in vision loss and update of section 4.8 of the SmPC to add the ADRs "blood testosterone decreased" and "oesophagitis", both with frequency 'common'.