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Press office

## Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 16-19 November 2015

Name of medicine	INN	Scope
Angiox	bivalirudin	CHMP opinion to update of sections 4.2 and 4.4 of the SmPC in order to update posology instructions and update warning on use of bivalirudin in case of haemorrhage.
Bronchitol	mannitol	PSUR assessment resulting in a variation to update sections 4.2 and 4.4 of the SmPC to recommend that patients must complete and pass the initiation dose assessment before treatment is started.
Caprelsa	vandetanib	PSUR assessment resulting in a variation to update section 4.4 of the SmPC to amend the wording on the warning on skin reactions.
Latuda	lurasidone	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reaction "tardive dyskinesia" with a frequency of "uncommon".



Name of medicine	INN	Scope
Lumigan	bimatoprost	PSUR assessment resulting in a variation to update section 4.8 of the SmPC of all bimatoprost formulations to add asthma, asthma exacerbation, COPD exacerbation, dyspnoea and hypersensitivity reactions including signs and symptoms of eye allergy and allergic dermatitis and to update section 4.8 of the SmPC of bimatoprost formulations 0.01% to add iris hyperpigmentation, macular oedema, blepharal pigmentation, periorbital and lid changes including deepening of the eyelid sulcus and dry eye.
Ofev	nintedanib	PSUR assessment resulting in a variation to update sections 4.4 and 4.8 of the SmPC to add a warning regarding the risk of haemorrhages and the adverse drug reaction "epistaxis".
Optaflu	influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reaction "paraesthesia" with a frequency "not known".
Simponi	golimumab	CHMP opinion to update section 4.4 of the SmPC to include information on diagnosing and management of invasive fungal infection in at-risk patients treated with Simponi.
Torisel	temsirolimus	PSUR assessment resulting in a variation to update section 4.4 of the SmPC to add warnings on myocardial infarction, anaemia and malignancies.
Trobalt	retigabine	New adverse reaction of vitelliform maculopathy identified requiring updates to section 4.4 of the SmPC (update of warning on eye disorders including changes to the ophthalmological examinations) and section 4.8 of the SmPC (addition of the adverse reaction, with a frequency of "common").
Velcade	bortezomib	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the preferred term "small intestinal obstruction" under the already listed general term "gastrointestinal obstruction".
Zinforo	ceftaroline	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reaction "eosinophilia" with a frequency "not known".