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Press office

## Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 23–26 May 2016

Name of medicine	INN	Scope
Cialis	tadalafil	PSUR assessment resulting in a variation to update section 4.8 of the SmPC of medicinal products containing tadalafil with the erectile dysfunction indication to add the adverse events 'nausea', 'fatigue', 'vomiting', and 'oedema peripheral', with an uncommon frequency, and to update the frequency of gastro-oesophageal reflux (from common to uncommon), hyperhidrosis, penile haemorrhage and haemospermia (from uncommon to rare) and prolonged erections (from rare to uncommon); to add a footnote on seizures and to delete a footnote on priapism; to add data regarding diarrhoea in elderly patients, in subsection other special population.
Conbriza	bazedoxifene	PSUSA assessment resulting in recommendation to include 'vision disorders/ ocular events' in section 4.8 of the SmPC.



Name of medicine	INN	Scope
Exjade	deferasirox	PSUR assessment resulting in a variation to update section 4.4 of the SmPC to revise the wording related to the warning on toxic epidermal necrolysis (TEN) and to update section 4.8 of the SmPC to add the adverse reactions 'acute pancreatitis' and 'toxic epidermal necrolysis (TEN)', both with a frequency not known. Section 'Paediatric population' under 4.8 of the SmPC should be also updated to warn of acute pancreatitis reported in children and adolescents.
Granupas	para-aminosalicylic acid	CHMP opinion to update sections 4.4 and 4.8 of the SmPC to include a warning and a description of the risk of hypothyroidism in HIV co-infected patients treated with a regimen containing para-aminosalicylic acid and ethionamide/ propionamide.
Harvoni	sofosbuvir / ledipasvir	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reaction 'rash' with a frequency common.
Jardiance, Synjardy	empagliflozin empagliflozin / metformin	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reactions 'blood creatinine increased' and 'glomerular filtration rate decreased' with a frequency uncommon.
Ofev	nintedanib	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add 'bleeding' with a frequency common, and 'pancreatitis' with a frequency uncommon' and to delete 'epistaxis'.
Plenadren	hydrocortisone	CHMP opinion to update section 4.4 of the SmPC to include information on the acute adrenal insufficiency.
Thalidomide Celgene	thalidomide	PSUR assessment resulting in a variation to update sections 4.4 and 4.8 of the SmPC to include warnings on viral reactivation and pulmonary hypertension and to reflect the case reports associated with treatment with thalidomide.