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Press office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 18-21 July 2016

Name of medicine	INN	Scope
Aluvia	lopinavir/ ritonavir	Update of sections 4.3 and 4.5 to add information regarding the interaction of lopinavir/ritonavir and dronedarone. In addition, Sections 4.3, 4.4 and 4.5 have been updated to include information regarding the contraindication with colchicine in patients with renal or hepatic impairment and in patients with normal renal or hepatic function if strong CYP3A4-inhibitor (such as ritonavir-boosted PI) is coadministered. The Labelling is updated accordingly. In addition the MAH took the opportunity to update sections 4.4 and 4.8 to change “immune reactivation syndrome” to “immune reconstitution inflammatory syndrome” to reflect current terminology.
Evoltra	clofarabine	PSUR resulting in an update of section 4.4 of the SmPC to include a new warning on the risk of renal failure and acute renal failure, and the need to monitor patients for renal toxicity. Update of section 4.8 of the SmPC to include ‘renal failure’, ‘acute renal failure’ as new adverse drug reactions with a ‘common’ frequency.

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Name of medicine	INN	Scope
Imbruvica	ibrutinib	Type II variation resulting in an update of section 4.4 of the SmPC with reference to cases of interstitial lung disease (ILD) in patients treated with Imbruvica. Update of section 4.8 of the SmPC to include IDL with a frequency “common”.
Kaletra	lopinavir/ ritonavir	Update of sections 4.3 and 4.5 to add information regarding the interaction of lopinavir/ritonavir and dronedarone. In addition, Sections 4.3, 4.4 and 4.5 have been updated to include information regarding the contraindication with colchicine in patients with renal or hepatic impairment and in patients with normal renal or hepatic function if strong CYP3A4-inhibitor (such as ritonavir-boosted PI) is coadministered. The Labelling is updated accordingly. In addition the MAH took the opportunity to update sections 4.4 and 4.8 to change “immune reactivation syndrome” to “immune reconstitution inflammatory syndrome” to reflect current terminology.
Revlimid	lenalidomide	PSUR resulting in an update of section 4.8 of the SmPC with the new adverse drug reaction ‘acquired haemophilia’ with the frequency ‘not known’.
Saxenda, Victoza	liraglutide	PSUR resulting in an update of section 4.8 of the SmPC to add the adverse reactions ‘increased lipase’ and ‘increased amylase’ with a frequency “common”.
Sovaldi	sofosbuvir	PSUR resulting in an update of sections 4.4, 4.5 and 4.8 of the SmPC to extend the warning regarding the risk of bradycardia when sofosbuvir is given with another direct-acting antiviral (DAA) and amiodarone. Furthermore, section 4.4 was updated to include possible risk factors of bradycardia with sofosbuvir plus another DAA and amiodarone.
Xolair	omalizumab	PSUR resulting in an update of section 4.8 of the SmPC to add the adverse drug reaction ‘systemic lupus erythematosus’ with a frequency ‘rare’.
Tracleer/ Stayveer	bosentan	PSUR resulting in an update of sections 4.7 and 4.8 of the SmPC to add the adverse reaction blurred vision with a frequency unknown.