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Press Office

## Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 23-26 March 2015

Name of medicine	INN	Scope
Aclasta	zoledronic acid	PSUR assessment resulting in a CHMP opinion to update sections 4.2, 4.4 and 4.8 of the SmPC to reflect the current knowledge on osteonecrosis of the jaw (ONJ). Annex II is updated to reflect the introduction of a patient reminder card with regards to the risk of ONJ.
Brinavess	vernakalant hydrochloride	PSUR assessment resulting in a CHMP opinion to update of section 4.4 and 4.8 of the SmPC to add information on cases of atrial flutter with 1:1 atrioventricular condition, which have been reported in the post-marketing setting. The package leaflet does not need to be updated.
Imnovid	pomalidomide	PSUR assessment resulting in a CHMP opinion to update the SmPC to add new adverse reactions and warnings as follows: hyperuricaemia (section 4.8), cardiac failure (sections 4.4 and 4.8), atrial fibrillation (section 4.8), angioedema (sections 4.4 and 4.8), urticaria (section 4.8), interstitial lung disease (ILD) (sections 4.4 and 4.8), hepatitis (sections 4.4 and 4.8) and increased blood uric acid (section 4.8).



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Increlex	mecasermin	PSUR assessment resulting in a CHMP opinion to update section 4.4 of the SmPC to include information regarding the possible occurrence of avascular necrosis in relation to slipped capital femoral epiphysis. The package leaflet does not need to be updated.
Januvia/Ristaben/ Tesabel/Xelevia	sitagliptin	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add bullous pemphigoid and arthropathy as adverse reactions with a frequency unknown. The package leaflet is updated accordingly.
Mirvaso	brimonidine	PSUR assessment resulting in a CHMP opinion to update section 4.4 to include the warning on erythema and flushing. Furthermore, update of section 4.8 to add the adverse reactions of swelling face and urticaria (reported from post-marketing data) with a frequency 'uncommon' and to reflect the warning from section 4.4 that aggravated erythema, flushing and skin burning sensation have been reported during the post-marketing period. The package leaflet is updated accordingly.
Selincro	nalmeffene	PSUR assessment resulting in a CHMP opinion to update section 4.3 of the SmPC to contraindicate the concomitant use with buprenorphine and methadone.
Temodal	temozolomide	PSUR assessment resulting in a CHMP opinion to update of section 4.4 of the SmPC to add a warning on opportunistic infections and reactivation of infections such as cytomegalovirus and hepatitis B virus. In addition, section 4.8 has been updated with the adverse reactions: cytomegalovirus infection, infection reactivation such as cytomegalovirus, hepatitis B virus and 'diabetes insipidus', with a frequency uncommon.
Xtandi	enzalutamide	PSUR assessment resulting in a CHMP opinion to update 4.4 and 4.8 of the SmPC to add a warning and update the safety information on posterior reversible encephalopathy syndrome (PRES), following the analysis of post-marketing case reports.
Exelon/Prometax	rivastigmine	Update of SmPC section 4.5 to include information on additive effects leading to bradycardia when rivastigmine is used concomitantly with beta-blockers and other bradycardic agents; furthermore, this section has also been updated with information that caution should be exercised when rivastigmine is co-administered with medicinal products which can induce <i>torsade de pointes</i> . Additionally, information that nicotine use increases the metabolism of rivastigmine in patients with Alzheimer's disease has been

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		included in the SmPC section 5.2.
Ariclaim Yentreve Cymbalta Xeristar	duloxetine	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add the adverse reaction cutaneous vasculitis with a frequency very rare. The package leaflet is updated accordingly.
Sonata	zaleplon	PSUR assessment resulting in a CHMP opinion to update sections 4.4, 4.5 and 4.7 of the SmPC to strengthen the information on the risk of next day effects on driving and mental alertness. The Package leaflet is updated accordingly.
Tergratin	bexarotene	PSUR assessment resulting in a CHMP opinion to update section 4.5 of the SmPC in order to strengthen the existing wording on interactions between bexarotene and insulin, agents enhancing insulin secretion or insulin-sensitisers in line with the current wording in section 4.4 of the SmPC. The Package leaflet is updated accordingly.