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Press Office

## Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 15-18 December 2014

Name of medicine	INN	Scope
Yellox	bromfenac	PSUR assessment resulting in a CHMP opinion to update of section 4.4 of the SmPC to add a warning on rebound effect of macular oedema. The Package leaflet is updated accordingly.
Victrelis	boceprevir	PSUR assessment resulting in a CHMP opinion to update of section 4.5 of the SmPC to add a new drug-drug interaction with maraviroc and update of section 4.8 of the SmPC to add renal impairment and glomerular filtration rate decreased as new adverse drug reaction with a frequency "unknown".
Lysodren	mitotane	PSUR assessment resulting in a CHMP opinion to update of section 4.4 and 4.5 of the SmPC to add the interaction with substances metabolized through cytochrome 3A4; update of section 4.4 of the SmPC to add a warning on the need for liver enzymes monitoring and update of section 4.2 and 4.4 of the SmPC to add information on the testing of plasma levels of mitotane.
Renagel	sevelamer hydrochloride	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add the adverse reaction "acidosis, increased serum chloride levels" with a frequency uncommon.

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Name of medicine	INN	Scope
Vidaza	azacitidine	PSUR assessment resulting in a CHMP opinion to update of section 4.4 and 4.8 of the SmPC to add necrotising fasciitis with a frequency unknown.
Effentora, Instanyl, PecFent	Fentanyl	PSUR assessment resulting in a CHMP opinion to update of sections 4.2, 4.5, 4.6, 4.8 and 5.1 of the SmPC to add new recommendations in case of discontinuation of therapy and interaction with partial opioid agonist/antagonists, and to add the adverse reactions of withdrawal syndrome, pyrexia and insomnia. In addition miosis has been added as a secondary pharmacological effect. The Package leaflet is updated accordingly.
Dynastat	parecoxib	CHMP opinion to update of SmPC Section 4.4 with information on increased risk of upper gastrointestinal (GI) complications including perforations, ulcers or bleedings when parecoxib is given concomitantly with glucocorticoids, selective serotonin reuptake inhibitors and with information on increased risk of bleeding during the concomitant use of NSAIDs with oral anticoagulants.
Olysio	simeprevir	CHMP opinion to update sections 4.4 and 4.5 of the SmPC in order reflect a recommendation not to combine simeprevir and ciclosporin in organ transplant patients and information on interactions and dose recommendation when simeprevir is co-administered with other immunosuppressants.
Sutent	sunitinib	PSUR assessment resulting in a CHMP opinion to update of section 4.4 of the SmPC to add that sunitinib should be used with caution in patients who are taking medicinal products that can prolong QT interval.
Cometriq	cabozantinib s-malate	CHMP opinion to update sections 4.4 and 4.5 of the SmPC regarding concomitant use with MRP2 inhibitors.
Lyrica, Pregabalin Pfizer	pregabalin	CHMP opinion to update sections 4.6 and 5.2 of the SmPC to reflect newly available PK data indicating that pregabalin is excreted into the human milk and that decision must be made whether to discontinue breast feeding or to discontinue pregabalin therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.