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Press Office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 21-24 October 2013

Name of medicine	INN	Scope
Alli	orlistat	CHMP opinion to update and clarify sections 4.3 and 4.5 of the Summary of Product Characteristics (SmPC) regarding information on the concomitant use of anti-HIV medicines.
Apidra	insulin glulisine	CHMP opinion to update sections 4.2, 4.4, 4.8 and 6.6 of the SmPC to warn about the risk of diabetic ketoacidosis when Apidra is administered in continuous subcutaneous insulin infusions, and to give advice on how to mitigate the risk.
Ariclaim, Cymbalta, Xeristar, Yentreve	duloxetine	CHMP opinion to update section 4.4 of the SmPC with information on serotonin syndrome and to include examples of monoamine oxidase inhibitors and serotonergic agents in section 4.5 of the SmPC.

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Gilenya	fingolimod	CHMP opinions to update sections 4.4, 4.5, 4.8 and 4.9 of the SmPC with: - information to specify how regularly a complete blood count should be performed. - information on the results of an interaction study with carbamazepine and a warning. - a description of the haemophagocytic syndrome following the report of 2 fatal cases. - updated information regarding infections and specifically disseminated herpes infections. - the deletion of the statement regarding the absence of cases of overdose reported with Gilenya. The CHMP endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the difficulties in diagnosing HPS and the importance of an early diagnosis as there is a risk of a worse outcome when the diagnosis and thus the treatment are delayed.
Hycamtin	topotecan	CHMP opinion to update sections 4.2 and 4.4 of the SmPC with data on patients with renal impairment from study HCT722 with oral Hycamtin.
Intelence	etravirine	PSUR assessment resulting in a CHMP opinion to update section 4.5 of the SmPC to add information about possible interactions with boceprevir.
Mabthera	rituximab	CHMP opinion to update section 4.4 of the SmPC in order to strengthen the warning regarding prevention of Hepatitis B reactivation. The CHMP endorsed a DHPC informing healthcare professionals to screen all patients for hepatitis B virus before starting treatment with Mabthera.
Soliris	eculizumab	CHMP opinion to update section 4.8 of the SmPC to list Aspergillus infections as an adverse drug reaction.
Xarelto	rivaroxaban	CHMP opinion to update section 4.4 of the SmPC regarding the risk of gastrointestinal disease without active ulceration that can potentially lead to bleeding complications (e.g. inflammatory bowel disease, oesophagitis, gastritis and gastroesophageal reflux disease).
Emend Ivemend	aprepitant fosaprepitant	PSUR assessment resulting in a CHMP opinion to update sections 4.5 of the SmPC to add a statement regarding the possible drug-drug interaction between aprepitant and ifosfamide.

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Benlysta	belimumab	PSUR assessment resulting in a CHMP opinion to update section 4.4 of the SmPC to add warning on delayed-type (non –acute) hypersensitivity and section 4.8 of the SmPC to add the adverse reaction "Delayed-type, non-acute hypersensitivity reactions" under the System Organ Class "Immune System disorders" with a frequency rare.
Lumigan	bimatoprost	PSUR assessment resulting in a CHMP opinion to update sections 4.4 and 4.8 of the SmPC and corresponding sections of the Patient Leaflet to amend the safety information to reflect the available data.
Bydureon	exenatide	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to move the following adverse reactions observed with exenatide from Table 2 (not observed with Bydureon) to Table 1 (Adverse reactions of Bydureon identified from clinical trials and spontaneous reports): "Renal and urinary disorder: Altered renal function, including acute renal failure, worsened chronic renal failure, renal impairment, increased serum creatinine (see section 4.4)." with the frequency 'not known'.
Yervoy	ipilimumab	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add the adverse reaction anaphylactic reactions with a frequency very rare. The Package leaflet is updated accordingly.
Xaluprine	mercaptopurine	PSUR assessment resulting in a CHMP opinion to update sections 4.4 and 4.8 of the SmPC to add a warning on hepatosplenic T cell lymphoma and lymphoproliferative disorders and to add the adverse reaction hepatosplenic T cell lymphoma and lymphoproliferative disorders with a frequency unknown.
Esbriet	pirfenidone	PSUR assessment resulting in a CHMP opinion to update sections 4.4 and 4.8 of the SmPC to add a reference to the elevations in total serum bilirubin which have been reported alongside elevations in AST/ALT in a small number of patients. The package leaflet has been updated to include symptoms that the patient should be aware of which may indicate liver problems.
Incivo	telaprevir	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add the adverse reaction prerenal azotemia with or without acute renal failure.

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Xgeva	denosumab	CHMP opinion to update section 4.8 of the SmPC to delete the ADR cellulitis and the text describing "skin infections (predominantly cellultis) leading to hospitalisation" and to delete the associated warning in SmPC section 4.4. Furthermore, section 4.8 of the SmPC has been updated with a change in frequency of the ADR drug hypersensitivity from uncommon to rare, and with the addition of text describing symptoms of hypocalcaemia observed in clinical studies.