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Press Office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 21-24 July 2014

Name of medicine	INN	Scope
Avonex Rebif Betaferon Extavia	interferon beta-1a interferon beta-1a interferon beta-1b interferon beta-1b	CHMP opinion to update sections 4.4 and 4.8 of the SmPC to add safety information with regards to thrombotic microangiopathy.
Cinryze	C1 inhibitor, human	PSUR assessment leading to an update of section 4.8 of the SmPC to include hypersensitivity.
Duocover/ Duoplavin	clopidogrel/ acetylsalicylic acid	CHMP opinion to update section 4.8 of the SmPC to add new adverse drug reactions Section 4.4 was also updated to include a warning related to patients with G6PD deficiency and risk of haemolysis. Information related to uncertainties with regard to alteration of fertility with ASA dose contained in ASA/clopidrogel fixed combination products in section 4.6 was also added.
Flebogamma DIF	human normal immunoglobulin	CHMP opinion to update section 4.4 of the SmPC with information on the need to monitor patient's vital signs when administering Flebogamma DIF to paediatric patients.

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Name of medicine	INN	Scope
Iclusig	ponatinib	PSUR assessment leading to an update of section 4.8 of the SmPC to reflect an increase in the frequency category for the following adverse reactions, which are already included: upper respiratory tract infection, insomnia, dizziness, eyelid oedema, aspartate aminotransferase increased, dermatitis exfoliative, muscle spasms, pain.
Ilaris	canakinumab	PSUR assessment leading to the following changes to the SmPC: • Update of sections 4.4 and 4.8 of the SmPC regarding opportunistic infections. • In addition update of section 4.9 of the SmPC regarding overdosage.
Incresync	alogliptin/ pioglitazone	CHMP opinion to update section 4.4 of the SmPC to include a warning related to drug combinations not studied (sulphonylurea, insulin).
Jevtana	cabazitaxel	PSUR assessment leading to an update of section 4.4 of the SmPC to amend the current warning on the risk of anaemia in patients treated with cabazitaxel.
Lucentis	ranibizumab	CHMP opinion to update section 4.2 of the SmPC in order to harmonise the administration instructions for Lucentis across indications in line with the available clinical evidence, relevant guidelines and treatment recommendations as well as clinical practice. The proposed posology recommendations for diabetic macular oedema are further supported by the final report of the RETAIN study. In addition, SmPC sections 4.5 and 5.1 were proposed to be updated to reflect RETAIN study data including data on the concomitant treatment with thiazolidinediones. The information in SmPC section 5.1 on the RESTORE study were also proposed to be updated with data from the 2-year extension phase as previously requested by the CHMP (MEA 035).
Mozobil	plerixafor	PSUR assessment leading to an update of section 4.8 of the SmPC to add “abnormal dreams” and “nightmares” as new adverse reactions with a frequency “uncommon”.
Prolia	denosumab	CHMP opinion to add the following changes in the SmPC: • Update section 4.4 of the SmPC, upon request by the PRAC following the assessment of PSU/027, to revise the warnings on osteonecrosis of the jaw; • To refine the warnings on hypocalcaemia including a description of the clinical manifestations of severe symptomatic hypocalcaemia and increases in parathyroid hormone in sections 4.4 and 4.8; • To add musculoskeletal pain as an identified risk in section 4.8 further to post-marketing experience.
Revlimid	lenalidomide	PSUR assessment leading to an update of section 4.8 of the SmPC to include gastrointestinal perforation.

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Rienso	ferumoxytol	PSUR assessment leading to the following changes in the SmPC: • Update of sections 1, 3, 4.2, 4.4, 6.2, 6.3, 6.4 and 6.6 to reflect that Rienso should only be administered as a 15-minute infusion. • Update of sections 4.2 and 4.4 to include a recommendation to carefully monitor patients for signs and symptoms of hypersensitivity (monitoring of blood pressure and pulse during and 30 minutes after administration) and that patients should be in a reclining/semi-reclining position during and after administration. • Update of section 4.3 to include a new contraindication in patients with any known drug allergy. • Update of sections 4.4 and 4.8 to include that fatal and life-threatening hypersensitivity reactions have been observed post-marketing.
Simulect	basiliximab	CHMP opinion to update section 4.4 of the SmPC to reflect that the prophylaxis of acute rejection in recipients of solid organ allografts other than renal has not been demonstrated and that in several small clinical trials in heart transplant recipients, serious cardiac adverse events such as cardiac arrest (2.2 %), atrial flutter (1.9%) and palpitations (1.4 %) have been reported more frequently with Simulect than with other induction agents.
Sutent	sunitinib	CHMP opinion to update section 4.4 of the SmPC to include a warning on hypoglycaemia and the need to temporarily interrupt treatment if hypoglycaemia occurs and regularly check blood glucose levels in diabetic patients to minimize the risk of hypoglycaemia.
Xgeva	denosumab	PSUR assessment leading to the following changes in the SmPC: • To revise the warnings in section 4.4 on osteonecrosis of the jaw (ONJ) and add information in sections 4.4 and 4.8 of the SmPC on the incidence of ONJ based on duration of exposure; • To refine the warnings on hypocalcaemia including a description of the clinical manifestations of severe symptomatic hypocalcaemia and increases in parathyroid hormone in sections 4.4 and 4.8; • To add musculoskeletal pain as an identified risk in section 4.8 further to post-marketing experience. • To update sections 4.2 and 5.3 of the SmPC have been updated with respect to recommendations for monitoring of calcium levels, and information regarding patients with renal impairment.