



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 18-21 May 2015

Name of medicine	INN	Scope
Circadin	melatonin	PSUR assessment resulting in a CHMP opinion to update of section 4.9 of the SmPC to add the information that cases of overdose have been reported post marketing with somnolence as the most reported adverse event. Most were mild to moderate in severity.
Gazyvaro	obinutuzumab	CHMP opinion to update the sections 4.2 and 4.4 of the SmPC by detailing the principles of prophylactic treatment and clinical monitoring of patients at risk of tumour lysis syndrome.
Halaven	eribulin	PSUR assessment resulting in a CHMP opinion to update of section 6.6 of the SmPC to add a warning on the need for flushing the intravenous line to ensure administration of the complete dose.
Jetrea	ocriplasmin	PSUR assessment resulting in a CHMP opinion to update of section 4.8 of the SmPC to include cystoid macular oedema, pupillary reflex impaired, and night blindness with the frequency "uncommon", and with information on occurrence of visual symptoms perceived in the contralateral eye or bilaterally.



Name of medicine	INN	Scope
Jevtana	cabazitaxel	CHMP opinion to update the sections 4.2, 4.3, 4.4 and 5.2 of the SmPC in order to add warnings and to update the safety information on the use of cabazitaxel in patients with hepatic impairment.
Latuda	lurasidone	PSUR assessment resulting in a CHMP opinion to update of sections 4.4 and 4.8 of the SmPC to add the adverse reaction neuroleptic malignant syndrome with the frequency "rare".
Mekinist	trametinib	CHMP opinion to update the sections 4.4 and 4.8 of the SmPC in order to add warnings regarding deep vein thrombosis (DVT) and pulmonary embolism (PE) and to update the safety information on haemorrhage.
Mycamine	micafungin	PSUR assessment resulting in a CHMP opinion to update of Annex II to include a further key element to the "Checklist for Prescribers" to highlight the restricted nature of the indications due to the important potential risk of hepatocellular carcinoma.
Opsumit	macitentan	PSUR assessment resulting in a CHMP opinion to update of section 4.8 of the SmPC to add nasal congestion with the frequency "common" and oedema, fluid retention with the frequency "very common".
Votrient	pazopanib	PSUR assessment resulting in a CHMP opinion to update of section 4.6 of the SmPC to add a warning on the need for contraception during treatment and at least 2 weeks after-treatment.
Exjade	deferasirox	PSUR assessment resulting in a CHMP opinion to update of section 4.4 of the SmPC to add a warning on deferasirox reintroduction after a hypersensitivity reaction (due to the risk of anaphylactic shock). This warning reinforces the existing contraindication on hypersensitivity.
Rapiscan	regadenoson	PSUR assessment resulting in a CHMP opinion to update of section 4.4 of the SmPC to communicate that respiratory arrest and bronchoconstriction can occur with regadenoson treatment and to clarify that appropriate bronchodilator therapy and resuscitative measures are available for all patients prior to regadenoson administration, and section 4.8 to add the adverse reactions respiratory arrest, wheezing and bronchospasm with a frequency of "not known", "uncommon" and "not known" respectively.
Zebinix	eslicarbazepine acetate	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add information on cutaneous adverse reactions and to revise the information on atrioventricular block. The package leaflet is updated accordingly.

Name of medicine	INN	Scope
Foclivia, Aflunov, Prepandemic influenza vaccine (H5N1)	pandemic / prepandemic influenza vaccines (H5N1) (surface antigen, inactivated, adjuvanted)	PSUR assessment resulting in a CHMP opinion to update section 4.4 of the SmPC to add a warning on syncope as a psychogenic response to the needle injection. The Package leaflet is updated accordingly.
Hexyon, Hexacima, Hexaxim	diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed)	CHMP opinion to update the section 4.5 of the SmPC with the information that co-administration of the hexavalent vaccine with meningococcal serogroup C vaccine does not lead to any clinically relevant interference in the antibody response to each of the antigens.
Stivarga	regorafenib	CHMP opinion to update the sections 4.2, 4.4 and 4.8 of the SmPC with the information that higher incidence of hand foot skin reaction (HFSR) / palmar-plantar erythrodysesthesia syndrome, severe liver function test abnormalities and hepatic dysfunction was observed in Asian (in particular Japanese) patients treated with Stivarga compared with Caucasians.