EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 22-25 September 2014

Name of medicine	INN	Scope
Iressa	gefitinib	CHMP opinion to update section 4.4 of SmPC regarding EGFR mutation assessment of the tumour tissue, which is recommended for all patients, when the use of gefitinib is considered as a treatment of locally advanced or metastatic NSCLC. If a tumour sample is not evaluable, then circulating tumour DNA (ctDNA) obtained from a blood (plasma) sample may be used.
Lojuxta	lomitapide	PSUR assessment leading to an update of section 4.5 of the SmPC to delete “ritonavir” and “tipranavir” from the list of weak CYP3A4 inhibitors.
Metalyse	tenecteplase	CHMP opinion to update section 4.4 of SmPC to add warning related to transfer to a timely coronary intervention. Information related to patients receiving oral anticoagulants was also added.
Valdoxan/ Thymanax	agomelatine	PSUR assessment resulting in a CHMP opinion to update sections 4.2 and 4.4 of the SmPC to monitor liver function and to include strengthening of the warning on liver monitoring.

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Xtandi	enzalutamide	CHMP opinion to update section 4.4 of SmPC to add information about co-administration with intravenous docetaxel.
Zaltrap	aflibercept	PSUR assessment leading to an update of sections 4.2 and 6.6 of the SmPC to include information regarding method of administration.
Elaprase	idursulfase	CHMP opinion to update sections 4.4 and 4.8 of the SmPC to reflect outcomes of the ongoing surveillance of anaphylactic reaction in patients treated with idursulfase (inclusion of the term “anaphylactic” and additional statement that these reactions may occur up to several years after initiating treatment). Additional amendments to section 4.3 and 4.4 were also agreed to reflect the fact that severe or life-threatening hypersensitivity to idursulfase or any of the excipients is a contraindication, if hypersensitivity is not controllable.
Xagrid	anagrelide	CHMP opinion to update of the SmPC sections 4.2, 4.4, 4.8, 5.1 and 5.2 in order to update the efficacy and safety information of anagrelide in the paediatric population based on the results from study SPD422-405 and SPD422-404. A warning on the risk of progression to AML and myelofibrosis and monitoring of signs and symptoms of disease progression have also been highlighted.
Victoza	liraglutide	CHMP opinion to update of section 4.4 of the SmPC in order to implement the recommendations of an Art 5(3) procedure on GLP-1-based therapies and pancreatic safety.
Aubagio	teriflunomide	PSUR assessment leading to an update of section 4.4 of the SmPC to add a warning on occurrence of Drug Reaction with Eosinophilia and Systemic Symptoms.
Humira	adalimumab	PSUR assessment leading to an update of section 4.8 of the SmPC to add vasculitis as a new adverse drug reaction with a frequency “uncommon”.
Bretaris Genuair	aclidinium bromide	PSUR assessment leading to an update of section 4.8 of the SmPC to add “palpitations” with a frequency of “uncommon”. The Package leaflet is updated accordingly.
Eklira Genuair	aclidinium	PSUR assessment leading to an update of section 4.8 of the SmPC to add “palpitations” with a frequency of “uncommon”. The Package leaflet is updated accordingly.
Kalydeco	ivacaftor	PSUR assessment leading to an update of section 4.4 of the SmPC to add to add a warning on cataracts.

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		The Package leaflet is updated accordingly
Leganto	rotigotine	PSUR assessment leading to an update of section 4.8 of the SmPC to add the adverse reactions “Delusion” and “Delirium” with a frequency rare and “CPK increased” with a frequency common, as proposed by the MAH. The Package leaflet is updated accordingly.
Neupro	rotigotine	PSUR assessment leading to an update of section 4.8 of the SmPC to add the adverse reactions “Delusion” and “Delirium” with a frequency rare and “CPK increased” with a frequency common, as proposed by the MAH. The Package leaflet is updated accordingly.
Tafinlar	dabrafenib	PSUR assessment leading to an update of section 4.4 of the SmPC to add a warning on RAS-mutation positive non-cutaneous malignancy associated with dabrafenib monotherapy treatment. The Package leaflet is updated accordingly.
Xaluprine	mercaptopurine	PSUR assessment leading to an update of section 4.8 of the SmPC to add photosensitivity reaction with a frequency “not known” and to add hypoglycaemia with a frequency “not known”. Add a warning on hypoglycaemia in section 4.4. The Package leaflet is updated accordingly.
Firmagon	degarelix	PSUR assessment leading to an update of section 4.2 of the SmPC to add clarifications in the drug administration schedule.
Imnovid	pomalidomide	PSUR assessment leading to an update of section 4.8 of the SmPC to add epistaxis (all adverse reactions) with a frequency of common and epistaxis (grade 3/4) with a frequency of uncommon. The Package leaflet is updated accordingly.
Nexavar	sorafenib	PSUR assessment leading to an update of section 4.8 of the SmPC in order to add encephalopathy as an adverse reaction with a frequency of unknown. The Package leaflet is updated accordingly.
Betmiga	mirabegron	PSUR assessment leading to an update of section 4.8 of the SmPC in order to add angioedema as an adverse reaction with a frequency of rare. The Package leaflet is updated accordingly.
Evoltra	clofarabine	PSUR assessment leading to an update of section 4.2 “Posology and method of administration” of the SmPC to specify that the recommended dose of 52 mg/m^2 should be used as monotherapy, in order to avoid using this dose in combination, and update of section 4.4 “Special warnings and precautions for use” of the

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		SmPC to add a warning regarding higher toxicity of clofarabine in association with other agents.