



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 April 2014

Name of medicine	INN	Scope
Gilenya	fingolimod	PSUR assessment leading to an update of section 4.8 of the SmPC to add "hypersensitivity" and "rash" as new adverse reactions. The Package Leaflet has been updated accordingly.
Gilenya	fingolimod	CHMP opinion to modify the indication to extend the patient population from patients with high disease activity despite treatment with a beta-interferon (IFN) to patients with high disease activity despite treatment with at least one disease modifying therapy. This results in an update of section 4.4 of the SmPC to include safety information relevant to switching from other immunosuppressive or immunomodulatory therapies to Gilenya. This mainly includes a recommendation to perform a complete blood count (CBC) prior to switching to Gilenya , guidance on appropriate washout periods for switch from teriflunomide and dimethyl fumarate and a warning that initiation of treatment with Gilenya after alemtuzumab is not recommended unless the benefits of such treatment clearly outweigh the risks for the individual patient. The Package Leaflet has been updated accordingly.

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Name of medicine	INN	Scope
Invega	paliperidone	CHMP opinion to extend the indication to the treatment of schizophrenia in adolescents 15 years and older. This results in an update of section 4.4 of the SmPC to recommend close monitoring for sedative side effect, extrapyramidal symptoms and regular clinical evaluation of endocrinological status due to the potential effects of prolonged hyperprolactinemia on growth and sexual maturation in adolescents.
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 nephrotic syndrome and glomerulosclerosis. The Package Leaflet has been updated accordingly.
Benlysta	belimumab	CHMP opinion to update section 4.4 of the SmPC to add a warning regarding progressive multifocal leukoencephalopathy.
Seebri Breezhaler, Enurev Breezhaler, Tovanor breezhaler	glycopyrronium bromide	PSUR assessment to update sections 4.2, 4.4 and 4.8 of the SmPC to add respectively a passage to target possible inadequate use of the device or drug, to add a warning on hypersensitivity and to add the adverse reactions hypersensitivity and angioedema with a frequency estimated according to the SmPC guideline.
Pradaxa	dabigatran etexilate	CHMP opinion to update section 4.5 of the SmPC to add a warning regarding the interaction between dabigatran and ticagrelor following the results of the drug-drug interaction (DDI) study. Sections 4.2 and 4.3 of the SmPC are also updated to increase the clarity of the recommendations in situation when switching from parenteral anticoagulant to dabigatran.
Incivo	telaprevir	CHMP opinion to update section 4.4 of the SmPC to revise the warning concerning the strategy for managing treatment-emergent anaemia.
Javlor	vinflunine ditartrate	PSUR assessment leading to an update of section 4.4 of the SmPC to add a warning on hyponatraemia and section 4.8 with minor amendments to the list of adverse reactions.

Name of medicine	INN	Scope
Osseor/ Protelos	strontium ranelate	PSUR assessment leading to an update of section 4.8 of the SmPC to add the adverse reaction "hypercholesterolaemia". Section 4 of the Package Leaflet has been updated accordingly.
Cayston	aztreonam	PSUR assessment leading to an update of section 4.4 of the SmPC to adjust an existing statement reflecting the fact that several reports of pruritus, urticaria, and erythema have been received during the reporting period.
Remicade	infliximab	Update of section 4.4 of the SmPC to mention that cases of active tuberculosis have been reported in patients treated with Remicade during and after treatment for latent tuberculosis. Update of section 4.4 and 4.8 of the SmPC to mention that the vast majority of HSTCL cases have occurred in patients with Crohn's disease or ulcerative colitis. The Package leaflet has been updated accordingly.
Evoltra	clofarabine	CHMP opinion to update of sections 4.4 and 4.8 of the SmPC to include warnings regarding reported cases of haemorrhage including fatal cases further to the PRAC/CHMP request following the assessment of PSUR 8. The Package leaflet has been updated accordingly.