18 December 2015
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Press office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 14-17 December 2015

Name of medicine	INN	Scope
Biopoin, Eporatio	epoetin theta	PSUR assessment resulting in a variation to update section 4.4 and 4.8 of the SmPC to mention that cases of neutralising anti-erythropoietin antibody-mediated pure red cell aplasia (PRCA) associated with epoetin theta therapy have been reported in the post-marketing setting. The package leaflet is updated accordingly.
Exviera, Viekirax	dasabuvir, ombitasvir/ paritaprevir/ ritonavir	CHMP opinion to update sections 4.2, 4.4, 4.8 and 5.2 of the SmPC in order to update the safety information based on post-marketing reports of hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes, and to add a warning that Viekirax/Exviera is not recommended in patients with moderate hepatic impairment (Child-Pugh B).
Gilenya	fingolimod	Update of sections 4.4 and 4.8 of the SmPC in order to update the safety information to include additional warning and guidance on PML. The Package Leaflet is updated accordingly.

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Name of medicine	INN	Scope
Jentadueto	linagliptin/ metformin hydrochloride	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reaction “bullous pemphigoid” with a frequency “unknown”. The package leaflet is updated accordingly.
Ketoconazole HRA	ketoconazole	PSUR assessment resulting in a variation to update section 4.5 of the SmPC with the interactions of ketoconazole with CYP3A4 substrates. The package leaflet is updated accordingly.
Methylthioninium chloride Proveblue	methylthioninium chloride	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reactions “injection site pain” and pain in extremity with a frequency “unknown”. The Package leaflet is updated accordingly.
Sovaldi	sofosbuvir	Type II variation to add the concomitant use of potent P-gp inducers as a contraindication in section 4.3. This follows the submission of the final study report evaluating the pharmacokinetic drug-drug interaction between sofosbuvir and rifampicin. Sections 4.4 and 4.5 and the PL will be updated accordingly.
Tarceva	erlotinib	Type II variation to limit indication to maintenance treatment to NSCLC patients with an EGFR-activating mutation based on the data from study BO25460 (IUNO).
Trajenta	linagliptin	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reaction “bullous pemphigoid” with frequency “unknown”. The package leaflet is updated accordingly.