



23 October 2015
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Press office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 19-22 October 2015

Name of medicine	INN	Scope
Aubagio	teriflunomide	PSUR assessment resulting in a variation to update section 4.4 of the SmPC to amend the wording on “Skin reactions” to more accurately reflect the available data to date from post-marketing setting; to update section 4.8 of the SmPC to change the frequency of “pancreatitis” to ‘not known’; to add “severe skin reactions”, “hypersensitivity reactions (immediate or delayed) including anaphylaxis and angioedema”, and “severe infections including sepsis” with a frequency ‘not known’; to add “CPK increase”, “arthralgia” and “palpitations” with a frequency ‘common’; to add “headache” with a frequency “very common”; and to include reference to amend the wording of the “peripheral neuropathy” section with the most up-to date figures based on clinical trial data.
Byetta, Bydureon	exenatide	PSUR assessment resulting in a variation to update sections 4.4, 4.5 and 4.8 of the SmPC to change the frequency of several side effects in line with updated clinical trials data.



Name of medicine	INN	Scope
Cellcept	mycophenolate mofetil	CHMP opinion to update the product information with a new contraindication during pregnancy, unless there are no suitable available alternatives (section 4.3) and to include additional related safety information (sections 4.4 and 4.6).
Cosentyx	secukinumab	CHMP opinion to update section 4.4 (in the context of two extensions of indication procedures) with the information that rare cases of anaphylactic reactions have been observed in patients receiving Cosentyx in clinical studies.
Fuzeon	enfuvirtide	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reaction "cutaneous amyloidosis" at the injection site.
Galvus, Jalra, Xiliarx, Eucreas, Zomarist, Icandra	vildagliptin, vildagliptin/metformin	PSUR assessment resulting in a variation to update section 4.5 of the SmPC to add the interaction with ACE inhibitors which could potentially lead to an increased risk of angioedema.
Invokana, Vokanamet	canagliflozin, metformin	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add "renal failure" with a frequency "uncommon".
Komboglyze, Onglyza	saxagliptin/metformin hydrochloride, saxagliptin	CHMP opinion to update sections 4.4 and 4.8 of the SmPC in order to add two new warnings related to arthralgia and hospitalization for heart failure.
Protopic	tacrolimus (topical formulations)	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add ophthalmic herpes infection with a frequency unknown. The Package leaflet is updated accordingly.
Stivarga	regorafenib	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to include clinically relevant information on severe liver injury, including the observed time to onset (within first 2 months), the hepatocellular pattern of liver injury and the information that a higher incidence of fatal liver injury has been observed in Japanese patients compared to non-Japanese patients treated with regorafenib.
Vfend	voriconazole	CHMP opinion to update section 4.4 with the information that a higher frequency of liver enzyme elevations was observed in the paediatric population.

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Vfend	voriconazole	PSUR assessment resulting in a variation to update the warning in section 4.4 on phototoxicity, and to add the adverse reactions "ephelides", "lentigo" and "actinic keratosis" to section 4.8.
Yervoy	ipilimumab	PSUR assessment resulting in a variation to update SmPC section 4.4 to add a warning on the risk of "Vogt-Koyanagi-Harada syndrome" and section 4.8 to add this adverse reaction with a frequency unknown.