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Press Office

## Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 17-20 November 2014

Name of medicine	INN	Scope
CellCept	mycophenolate mofetil	CHMP opinion to update sections 4.4 and 4.8 of the SmPC to add a warning and update the safety information on bronchiectasis and hypogammaglobulinemia. The package leaflet is updated accordingly.
Latuda	lurasidone	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to include "hypersensitivity" with a frequency of "unknown". The package leaflet is updated accordingly.
Optaflu	influenza vaccine - surface antigen, inactivated, prepared in cell cultures	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add the adverse reaction "extensive limb swelling" with a frequency "not known".
Sancuso	granisetron	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to include "hypersensitivity reactions" with a frequency of "unknown". The package leaflet is updated accordingly.



Name of medicine	INN	Scope
Simponi	golimumab	PSUR assessment resulting in a CHMP opinion to update section 6 of the package leaflet for the pre-filled pen to clarify instructions on the use of the auto-injector.
Xyrem	sodium oxybate	CHMP opinion to update sections 4.4 and 4.5 of the SmPC with a warning against concomitant use of sodium oxybate with topiramate. This is based on clinical observations of coma and increased plasma gamma-hydroxybutyrate concentration after co-administration of sodium oxybate with topiramate.
Rapiscan	regadenoson	PSUR assessment resulting in a request for a DHPC for communication regarding the risks of haemorrhagic cerebrovascular accident, the risk of prolongation/worsening of regadenoson-induced seizures due to the administration of aminophylline, and the risk of elevated blood pressure.
Vipidia, Vipdomet, Incresync	alogliptin, alogliptin, metformin, alogliptin, pioglitazone	PSUR assessment resulting in a CHMP opinion to update section 4.4 of the SmPC to add a warning that among hypersensitivity reactions, erythema multiforme has been observed post marketing and to update 4.8 of the SmPC to add "erythema multiforme" with a frequency "unknown". The package leaflet is updated accordingly.
Bydureon, Byetta	exenatide	PSUR assessment resulting in a CHMP opinion to update section 4.4 of the SmPC to revise a warning on occurrence of cholelithiasis, linked to the rapid weight loss during exenatide treatment.
Bydureon	exenatide	PSUR assessment resulting in a CHMP opinion to update section 4.4 of the SmPC to revise a warning on occurrence of cholelithiasis, linked to the rapid weight loss during exenatide treatment.  Furthermore, update of section 4.8 of the SmPC of exenatide administered once weekly, to reflect the current experience with the post-marketing use of exenatide administered once weekly and evidence the spontaneous reports of several adverse reactions and their frequencies.
Opsumit	macitentan	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC regarding hypersensitivity reactions (e.g. angioedema, rash, pruritus) with a frequency uncommon. The package leaflet is updated accordingly.