



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2016
EMA/76609/2016
Press office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 20-23 June 2016

Name of medicine	INN	Scope
Benlysta	belimumab	CHMP opinion to update of section 4.4 of the SmPC in order to add information on effect of Benlysta on vaccine responses based on results from study BEL115470 (HGS1006-C1117).
Halaven	eribulin	PSUR resulting in an update of section 4.8 of the SmPC to add Stevens Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) as adverse reactions with frequency "not known".
Jakavi	ruxolitinib	CHMP opinion to update sections 4.2 and 4.5 of the SmPC in order to include information that the concomitant use of Jakavi with fluconazole doses greater than 200 mg daily should be avoided.
Ketoconazole HRA	ketoconazole	PSUR assessment resulting in an update to section 4.5 of the SmPC on interactions with crizotinib, ibrutinib and the direct-acting antiviral (DAAV) combination of ombitasvir-paritaprevir-ritonavir. Section 4.3 of the SmPC was also updated to include contraindication with the use of the DAAV combination of ombitasvir-paritaprevir-ritonavir.

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5550

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Mekinist	trametinib	PSUR assessment resulting in an update of the existing SmPC 4.4 warnings on left ventricular ejection fraction (LVEF) reduction/left ventricular dysfunction, and update of section 4.8 of the SmPC to add the adverse reaction myocarditis with a frequency unknown for trametinib and dabrafenib combination therapy.
Noxafil	posaconazole	CHMP opinion to update of section 4.2 of the SmPC in order to strengthen the information about non-interchangeability of the oral formulations based on new reports of medication errors related to confusion between posaconazole tablets and oral suspension in prescribing.
Olysio	simeprevir	PSUR assessment resulting in an update of section 4.8 of the SmPC to add information about hepatic failure symptoms in patients at risk of hepatic decompensation and failure with the use of simeprevir.
Renagel, Renvela, Sevelamer carbonate Zentiva, Tasermit	sevelamer	PSUSA assessment resulting in an update of section 4.4 to add a warning regarding gastrointestinal disorders associated with sevelamer crystals.
Vargatef	nintedanib	PSUR assessment resulting in an update of section 4.4 and 4.8 of the SmPC to add a warning on "gamma-glutamyltransferase increased", and to add the adverse reaction "gamma-glutamyltransferase increased" with a frequency "common".
Xalkori	crizotinib	CHMP opinion to update section 4.4 and 4.8 of the SmPC with regards to the effect of crizotinib on renal function following a retrospective review of renal safety data from clinical studies A8081014 (1014), A8081007, (1007), A8081005 (1005), and A8081001 (1001).
Cancidas	caspofungin	CHMP opinion to update of sections 4.4, 4.8 of the SmPC in order to add warning on serious cutaneous reactions and to include the new ADRs "toxic epidermal necrolysis" and "Stevens-Johnson Syndrome" with the frequency 'not known' based on the post-marketing experience.