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Press Office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 19-22 May 2014

Name of medicine	INN	Scope
Arava/ Leflunomide Winthrop	leflunomide	CHMP opinion to update of sections 4.4 and 4.8 of the SmPC to include a warning on drug reaction with eosinophilia and systemic symptoms and to add this as an adverse reaction. The package leaflet will be updated accordingly.
Bosulif	bosutinib	CHMP opinion to update sections 4.2, 4.4 and 5.2 of the SmPC further to data in patients with renal impairment, supporting dose reduction recommendations in patients with moderate and severe renal impairment. The package leaflet will be updated accordingly.
Bydureon	exenatide	PSUR assessment to update section 4.8 of the SmPC to add "injections site abscess and cellulitis" as a new adverse reaction with unknown frequency, and to include a new statement on reports of post-marketing cases. The package leaflet will be updated accordingly.



Name of medicine	INN	Scope
Dacogen	decitabine	PSUR assessment to update section 4.8 of the SmPC to reflect the risk of enterocolitis, including neutropenic colitis and caecitis. The package leaflet will be updated accordingly.
Diacomit	stiripentol	CHMP opinion to update section 4.2 of the SmPC in order to adjust the dosage by age and to reduce dosing increments for higher doses. The package leaflet will be updated accordingly.
Inlyta	axitinib	CHMP opinion to update sections 4.4 and 4.8 of the SmPC with regards to cardiac failure events reported with a frequency "common". Signs or symptoms of cardiac failure should periodically be monitored throughout treatment with axitinib. Management of cardiac failure events may require temporary interruption or permanent discontinuation and/or dose reduction of axitinib therapy. The package leaflet will be updated accordingly.
Rapiscan	regadenoson	PSUR assessment leading to an update sections 4.2, 4.4 and 4.8 of the SmPC to introduce warnings on the risks of haemorrhagic cerebrovascular accident, prolongation/worsening of regadenoson-induced seizures due to the administration of aminophylline, and the risk of elevated blood pressure. The package leaflet will be updated accordingly.
Revestive	teduglutide	CHMP opinion to update sections 4.2, 4.4, 4.8 and 5.1 of the SmPC with the results of a long-term open label study. Due to the relative high occurrence of gastrointestinal polyps in patients who were treated with Revestive for one to two years, a recommendation to perform follow-up colonoscopies (or alternative imaging) during the first two years of treatment has been included. The package leaflet will be updated accordingly.
Sancuso	granisetron	PSUR assessment leading to an update sections 4.4 and 4.5 of the SmPC to introduce a class warning on the risk of developing "serotonin syndrome" with 5-HT3 antagonists, mostly when used with other serotonergic agents. The package leaflet will be updated accordingly.
Zytiga	abiraterone	PSUR assessment leading to an update of section 4.8 of the SmPC to include myocardial infarction. The package leaflet will be updated accordingly.
Nimenrix	Meningococcal group a, c, w135 and y conjugate vaccine	PSUR assessment leading to an update of section 4.8 of the SmPC to add "extensive limb swelling at injection site, frequently associated with erythema, sometimes involving the adjacent joint or swelling of the entire injected limb" as a new adverse drug reaction with a frequency of rare. The package leaflet will be updated accordingly.