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Press Office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 24-27 June 2013

Name of medicine	INN	Marketing authorisation holder	Scope
Aprovel	irbesartan	Sanofi Pharma Bristol-Myers Squibb SNC	CHMP opinion to update sections 4.3, 4.4 and 4.5 of the SmPC to inform prescribers that the concomitant use of angiotensin II receptor blockers (ARBs) with aliskiren is contraindicated in patients with renal impairment and in patients with diabetes mellitus.
Karvea		Sanofi-Aventis Groupe	
Irbesartan Zentiva		Sanofi-Aventis Groupe	
CoAprovel	irbesartan/ hydrochlorothiazide	Sanofi Pharma Bristol-Myers Squibb SNC	
Karvezide		Sanofi-Aventis Groupe	

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Name of medicine	INN	Marketing authorisation holder	Scope
Irbesartan hydrochlorothiazide Zentiva		Sanofi-Aventis Groupe	
Cystagon	mercaptamine bitartrate	Orphan Europe S.A.R.L.	CHMP opinion to update sections 4.4 and 4.8 of the SmPC regarding the figures on the reported cases of nephrotic syndrome and in order to expand the warning on skin reactions reported in children treated with high doses of Cystagon to any other vascular elbow lesions in an attempt to better reflect and characterise these reactions.
Exforge HCT	amlodipine/ valsartan/ hydrochlorothiazide	Novartis Europharm Ltd	CHMP opinion to update sections 4.2, 4.3, 4.4 and 4.5 of the SmPC to inform prescribers that the concomitant use of angiotensin II receptor blockers (ARBs) or angiotensin converting enzyme (ACE) inhibitors with aliskiren is contraindicated in patients with renal impairment and in patients with diabetes mellitus. The update also includes recommendations for prescribers to monitor blood pressure, renal function and electrolytes when co-administering agents acting on the renin angiotensin aldosterone system (RAAS).
Copalia HCT			
Dafiro HCT			
Exforge	amlodipine/ valsartan		
Copalia			
Dafiro			
Imprida			
Remicade	infliximab	Janssen Biologics B.V.	CHMP opinion to update sections 4.4 and 4.5 of the SmPC to add information regarding the administration of live vaccines and therapeutic infectious agents concurrently with Remicade and Simponi.
Simponi	golimumab		

Taxotere	docetaxel	Aventis Pharma S.A.	CHMP opinion to update sections 4.4 and 4.8 of the SmPC with a warning and safety information on the risk of cystoid macular oedema.
Docetaxel Winthrop	docetaxel		
Torisel	temsirolimus	Pfizer Limited	CHMP opinion to update sections 4.4 and 4.8 of the SmPC with a warning and safety information on *Pneumocystis jiroveci* pneumonia.
Tysabri	natalizumab	Biogen Idec Limited	CHMP opinion to update section 4.4 of the SmPC with a warning that anti-John Cunningham virus (JCV) antibody negative patients may still be at risk of progressive multifocal leukoencephalopathy (PML) for reasons such as a new JCV infection, fluctuating antibody status or a false negative test result.
Vectibix	panitumumab	Amgen Europe B.V.	CHMP opinion to update sections 4.1, 4.2, 4.3, 4.4, 4.5 and 5.1 of the SmPC following a restriction in the indication to patients with established wild-type RAS (i.e. KRAS and NRAS) tumours. The contraindication against combination with FOLFOX in patients with mutant RAS tumours, as well as the relevant posology recommendation, warning and drug-drug interaction warning are being updated accordingly. The CHMP endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.
Myocet	Doxorubicin	Teva Pharma B.V.	CHMP opinion to update section 4.8 of the SmPC with palmar – plantar erythrodysaesthesia syndrome with a frequency category “not known”. The package leaflet was updated accordingly.
Victrelis	boceprevir	Merck Sharp & Dohme	CHMP opinion to update section 4.5 of the SmPC with a warning on the interaction between boceprevir and calcium channel antagonists.
Eliquis	apixaban	Pfizer ltd	CHMP opinion to update sections 4.3 and 4.9 of the SmPC in relation to bleeding risk and management of overdose related to bleeding risk.
Xarelto	rivaroxaban	Bayer Pharma AG	CHMP opinion to update section 4.3 of the SmPC in relation to bleeding risk identical for all strengths and indications.

Keppra	levetiracetam	UCB Pharma SA	CHMP opinion to update sections 4.5, 4.6 and 4.8 of the SmPC to include information on the interaction between levetiracetam and macrogol-containing laxatives, to add the rare adverse drug reaction agranulocytosis as well as to include information on the cumulative experience in women exposed to levetiracetam during pregnancy and the increased risk of congenital malformation of antiepileptic polytherapy compared to levetiracetam monotherapy.
Foscan	temoporfin	Biolitec pharma LTD	CHMP opinion to update of sections 4.4 and 4.8 of the SmPC to add fistula, sepsis, headache, onset and duration of pain, vascular rupture and tongue oedema. In addition section 4.4 has been updated to include a warning on the risk of cholangitis, cholecystitis, liver abscess and oesophageal perforation and a recommendation to use headlamps in case that emergency surgery is needed. The package leaflet has been updated accordingly. Furthermore, Annex II has been updated to include the condition to operate a Risk Management System and submit a Risk Management Plan and to bring in line with the latest QRD template version 9.0.
Onbrez Breezhaler Oslif Breezhaler Hirobriz Breezhaler	indacaterol	Novartis Europharm Ltd.	CHMP opinion to update section 4.4 of the SmPC to include information on serious asthma related events observed as a class effect for LABAs when used to treat asthma and to revise the wording regarding QT-prolongation for indacaterol and as a class effect for LABAs.
Tarceva	erlotinib	Roche Registration Ltd	CHMP opinion to update of section 4.4 of the SmPC to include a warning on testing for skin infection for patients with bullous and exfoliative skin disorders and a modification of the warning on nephrotoxicity; Furthermore update of sections 4.4 and 4.8 regarding the higher incidence of interstitial lung disease in Japanese patients and update of section 4.5 of the SmPC to add a section on interactions with Proteasome inhibitors including bortezomib. The Package Leaflet has been updated in accordance.