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Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 21-24 May 2012

Name of medicine	INN	Marketing authorisation holder	Scope
Vectibix	panitumumab	Amgen Europe B.V.	CHMP opinion recommending changes to sections 4.4 and 4.8 of the SmPC to include information on life-threatening infections following severe skin reactions. The CHMP has endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.
CoAprovel	irbesartan/ hydrochlorothiazide	Sanofi Pharma Bristol-Myers Squibb SNC	CHMP opinion recommending changes to sections 4.4 and 4.8 of the SmPCs to include information on the risk of 'acute myopia' and 'secondary acute angle-closure glaucoma' associated with the use of hydrochlorothiazide.
Karvezide		Bristol-Myers Squibb Pharma EEIG	
Irbesartan HCT Zentiva		Sanofi-aventis	

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Exforge HCT	amlodipine/ valsartan/ hydrochlorothiazide	Novartis Europharm Ltd.	CHMP opinion recommending changes to sections 4.2, 4.4, 4.5, 4.6, 4.8 and 5.2 of the SmPCs to update the safety and pharmacokinetic information related to the hydrochlorothiazide component of the fixed-dose combination. Sections 4.4 and 4.8 of the SmPCs have been updated to include information on the risk of 'acute angle-closure glaucoma' associated with the use of hydrochlorothiazide.
Copalia HCT		Novartis Europharm Ltd.	
Dafiro HCT		Novartis Europharm Ltd.	
Imprida HCT		Novartis Europharm Ltd.	
Ecalta	anidulafungin	Pfizer Limited	CHMP opinion recommending changes to sections 4.2, 4.4, 4.6 and 4.8 of the SmPC to include warnings on anaphylactic reactions and infusion-related reactions. Anaphylactic shock and anaphylactic reaction were included as adverse events.
Invega	paliperidone	Janssen-Cilag International NV	CHMP opinion recommending changes to sections 4.4 and 4.8 of the SmPC with new recommendations on the monitoring of patients and the discontinuation of treatment in relation to low white blood cell count.
Xeplion	paliperidone palmitate	Janssen-Cilag International NV	