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Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 27-30 May 2013

Name of medicine	INN	Marketing authorisation holder	Scope
Bridion	sugammadex	N.V. Organon	CHMP opinion to update sections 4.4 and 4.8 of the SmPC with information on bradycardia, following review of post-marketing data.
Fampyra	fampridine	Biogen Idec	CHMP opinion to update sections 4.4 and 4.8 of the SmPC with information on hypersensitivity reactions (including anaphylaxis).
Jevtana	cabazitaxel	Sanofi-Aventis Groupe	CHMP opinion to update sections 4.4 and 4.8 of the SmPC with information on gastrointestinal complications (including haemorrhage and perforation, ileus, colitis).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8669
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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Pixuvri	pixantrone	CTI Life Sciences Limited	CHMP opinion to update sections 2 and 4.2 of the SmPC to clarify the expression of strength in order to address a potential risk of confusion in the dose to be administered. The CHMP endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.
Suboxone	buprenorphine/ naloxone	RB Pharmaceuticals Ltd	CHMP opinion to update sections 4.2, 4.4, 4.5, 4.6 and 4.8 of the SmPC with new or revised information on withdrawal signs, respiratory depression (in non-opioid dependent individuals, children and pregnant women), hepatic injury, severe renal impairment as well as a general warning on the administration of opioids, and interaction with opioid agonists.
Thalidomide Celgene	thalidomide	Celgene Europe Limited	CHMP opinion to update section 4.8 of the SmPC to add posterior reversible encephalopathy syndrome (PRES) as an adverse reaction.
Xeloda	capecitabine	Roche Registration Ltd	CHMP opinion to update section 4.4 of the SmPC with a warning related to ophthalmologic complications and their management. In addition, section 4.8 is updated to include cutaneous lupus erythematosus and ophthalmologic complications (corneal disorders, keratitis, punctate keratitis) as adverse events.
Yervoy	ipilimumab	Bristol-Myers Squibb Pharma EEIG	CHMP opinion to update section 4.4 of the SmPCs of both medicinal products to include a warning that the concurrent administration of ipilimumab and vemurafenib is not recommended. The SmPC is amended following phase I trial results which showed asymptomatic increases in liver enzymes.
Zelboraf	vemurafenib	Roche Registration Ltd	
Zytiga	abiraterone	Janssen-Cilag International N.V.	CHMP opinion to update sections 4.4 and 4.8 of the SmPC to include a warning regarding skeletal muscle effects (myopathy, rhabdomyolysis) and to add diarrhoea, myopathy and rhabdomyolysis as adverse drug reactions in

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			the course of treatment with Zytiga.
Conbriza	bazedoxifene	Pfizer Limited	CHMP opinion to update section 4.8 of the SmPC to add the adverse reactions palpitations, rash and pruritus with frequency unknown, under the appropriate SOC. The Package Leaflet has been updated accordingly.
Circadin	melatonin	RAD Neurim Pharmaceuticals EEC Ltd	CHMP opinion to update section 4.2 of the SmPC to reduce the risk of medication errors through reinforcement of the existing statement “Tablets should be swallowed whole”, i.e. by addition that “crushing or chewing should not be used to facilitate swallowing”. Section 4.8 of the SmPC was amended to include nausea, galactorrhoea, hypersensitivity reaction, angioedema, oedema of mouth and tongue oedema as adverse reactions. The Package leaflet has been updated accordingly.
Signifor	pasireotide disapartate	Novartis Europharm Ltd	CHMP opinion to update section 4.8 of the SmPC to correct the frequency allocated to the adverse reaction ‘anaemia’ to ‘uncommon’ and section 4.4 of the SmPC with a minor change to the wording for the existing warning on hyperglycaemia. The Package leaflet has been updated accordingly.