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Press office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 12-15 September 2016

Name of medicine	INN	Scope
Abraxane	paclitaxel	PSUR assessment resulting in an update of section 4.5 of the SmPC to include a warning on the interaction of paclitaxel with clopidogrel. The variation includes also a warning on the potential increase of toxicity when paclitaxel is concomitantly used with medicines known to induce CYP2C8 or CYP3A4.
Blincyto	blinatumomab	CHMP opinion to update sections 4.4 and 4.8 of the SmPC to add a warning about pancreatitis, and to emphasise the mitigation of the risk of cytokine release syndrome.
Erivedge	vismodegib	PSUR assessment resulting in an update of section 4.4 of the SmPC to amend the current warning on the initial prescription and dispensing of Erivedge which should occur within 7 days of a negative pregnancy test to specify that the day of the negative pregnancy test should count as day 1. Consequently Annex II.D was updated to reflect the revised warning in the educational materials.
Erivedge	vismodegib	CHMP opinion to update sections 4.2, 4.4 and 4.8 of the SmPC with additional information to describe the risk of epiphyses premature fusion in paediatric patients.

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Name of medicine	INN	Scope
Giotrif	afatinib	CHMP opinion to update section 4.4 of the SmPC in order to add toxic epidermal necrolysis to the existing warning on skin-related adverse events and update of section 4.8 of the SmPC to add toxic epidermal necrolysis/Stevens-Johnson syndrome with a frequency rare.
Harvoni	sofosbuvir / ledipasvir	CHMP opinion to update section 4.4 of the SmPC in order to state that limited data on the use of Harvoni in patients with HCV/HBV co-infection are available.
Kaletra	lopinavir/ ritonavir	CHMP opinion to update sections 4.4 and 4.5 of the SmPC in order to include a warning and information regarding the interaction of Kaletra with afatinib, riociguat, cetirinib and vorapaxar.
Keppra	levetiracetam	PSUR assessment resulting in an update of sections 4.4 and 4.8 of the SmPC to add safety information regarding the risks of acute kidney injury, encephalopathy, rhabdomyolysis and blood dyscrasias.
Mirvaso	brimonidine	PSUR assessment resulting in an update of section 4.8 of the SmPC to include 'pallor at the application site' with a frequency common.
Picato	ingenol mebutate	PSUR assessment resulting in an update of section 4.8 of the SmPC to include 'application site scarring' as a new adverse drug reaction with a rare frequency.
Selincro	nalmefene	PSUR assessment resulting in an update of section 2 of the Package Leaflet to include references to methadone and buprenorphine (already mentioned in the SmPC) as examples of opioid substances that are contraindicated. This update was considered to further minimise the existing problem of concomitant use of opioids despite their contraindication.
Teysono	tegafur/ gimeracil/ oteracil	PSUR assessment resulting in an update of section 4.8 of the SmPC to include limbal stem cell deficiency in the ADR table regarding corneal disorders.
Thymanax, Valdoxan	agomelatine	PSUR assessment resulting in an update of section 4.4 and 4.8 of the SmPC to add a warning for "alcohol use disorder" and add the adverse reaction akathisia with a frequency rare.
Emtriva	emtricitabine	CHMP opinion to update sections 4.2, 4.4 and 4.8 of the SmPC in order to allow administration of Emtriva 200 mg hard capsule every 24 to 48 hours in patients with renal impairment (eGFR _{CG} ≥ 30mL/min) and corresponding update the SmPC for Emtriva 10mg/ml oral solution.