2 May 2013
EMA/CHMP/184564/2013
Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 22-25 April 2013

Name of medicine	INN	Marketing authorisation holder	Scope
Abilify	aripiprazole	Otsuka Pharmaceutical Europe Ltd.	CHMP opinion to update section 4.4 to add to the existing warning on risk of suicide that there are insufficient paediatric data to evaluate the risk of suicide with aripiprazole compared to other antipsychotics in younger patients (below 18 years of age), but there is evidence that the risk persists beyond the first 4 weeks of treatment for atypical antipsychotics, including aripiprazole. This updated warning is based on the results of an epidemiological study submitted in accordance with Article 46 of the Paediatric Regulation (EC) No 1901/2006.

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Name of medicine	INN	Marketing authorisation holder	Scope
Avastin	bevacizumab	Roche Registration Ltd	CHMP opinion to update sections 4.4 and 4.8 of the SmPC with the addition of necrotising fasciitis. The Package Leaflet has been updated accordingly. In addition section 4.8 of the SmPC has been updated to add the incidence of gastrointestinal perforations in metastatic renal cell cancer patients.
Orencia	abatacept	Bristol-Myers Squibb Pharma EEIG	CHMP opinion to update section 4.4 regarding allergic reactions and to include further recommendations on the permanent discontinuation of Orencia in case of serious allergic or anaphylactic reactions. The patient alert card has been updated accordingly to include information on the risk of systemic hypersensitivity reactions.
Samsca	tolvaptan	Otsuka Pharmaceutical Europe Ltd	CHMP opinion to update sections 4.4 and 4.8 of the SmPC with information on increased risk of serious liver injury observed in clinical trials investigating a different potential indication (autosomal dominant polycystic kidney disease) for tolvaptan. The CHMP endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.
Pradaxa	dabigatran etexilate	Boehringer Ingelheim International GmbH	CHMP opinion to update sections 4.2, 4.4, 4.5 and 5.2 of the SmPC to include new information related to the drug interaction with ticagrelor.
Pradaxa	dabigatran etexilate	Boehringer Ingelheim International GmbH	CHMP opinion to update section 4.3 of the SmPC with the contraindication on lesions and conditions at significant risk of major bleeding. The wording has been revised to allow the prescribing physician more room for clinical judgment on when to consider the listed lesions and conditions as absolute contraindications. The summary of this opinion can be found on the European Medicines Agency's website under the April CHMP meeting highlights.

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Kinzalkomb	telmisartan / hydrochlorothiazide	Bayer Pharma AG	CHMP opinion to update sections 4.2, 4.3, 4.4 and 4.5 of the SmPC to include recommendations regarding the use of telmisartan with aliskiren. The contraindication section is amended with the following information added in section 4.3: "*The concomitant use of telmisartan with aliskiren is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m^2) (see sections 4.2, 4.4, 4.5)*." Corresponding changes have been introduced in sections 4.2, 4.4 and 4.5. These changes were implemented as a consequence of the Periodic Safety Update Report assessment and the review of aliskiren-containing medicines under Article 20 of Regulation (EC) No 726/2004. In addition, information related to interaction with digoxin is added in section 4.5 of the SmPC. The Package leaflet has been updated accordingly. The summary of this opinion can be found on the European Medicines Agency's website under the April CHMP meeting highlights.
Kinzalmono	telmisartan	Bayer Pharma AG	
Micardis	telmisartan	Boehringer Ingelheim International GmbH	
MicardisPlus	telmisartan / hydrochlorothiazide	Boehringer Ingelheim International GmbH	
Onduarp	telmisartan / amlodipine	Boehringer Ingelheim International GmbH	
Pritor	telmisartan	Bayer Pharma AG	
PritorPlus	telmisartan / hydrochlorothiazide	Bayer Pharma AG	
Twynsta	telmisartan / amlodipine	Boehringer Ingelheim International GmbH	
Gilenya	fingolimod	Novartis Europharm Ltd	CHMP opinion to update section 4.4 regarding the existing warning on bradyarrhythmia to reflect that the post-dose effect persists over the following days, although usually to a milder extent, and usually abates over the next weeks. With continued administration, the average heart rate returns towards baseline within one month. However individual patients may not return to baseline heart rate by the end of the first month. In addition, section 4.8 has been updated regarding the occurrence of lymphoma.