



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 16-19 July 2012

Name of medicine	INN	Marketing authorisation holder	Scope
Avastin	bevacizumab	Roche Registration Ltd	CHMP opinion recommending to update section 4.4 of the SmPC in order to revise the wording on the adverse reactions that have been reported from unauthorised intravitreal use of Avastin based on recently published clinical trials.
Macugen	pegatanib sodium	Pfizer Ltd.	CHMP opinion recommending to update sections 4.2, 4.4, 4.8 and 6.6 of the SmPC in order to include a warning on the risk of serious increase of intraocular pressure following intravitreal administration of the incorrect volume of Macugen and improve and clarify the instructions for use of Macugen. The CHMP endorsed a Direct Healthcare Professional Communication (DHPC)

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			informing healthcare professionals of the revised recommendations.
Ozurdex	dexamethasone	Allergan Pharmaceuticals Ireland	CHMP opinion recommending to update sections 4.3, 4.4 and 4.8 of the SmPC to include a contraindication for use in "aphakic eyes with rupture of the posterior lens capsule" and "eyes with anterior chamber intraocular lens (ACIOL) and rupture of the posterior lens capsule". Section 4.4 has been updated to amend the warning related to posterior capsule tear. "Hypotony of eye (associated with vitreous leakage due to injection)" and "Complication of device insertion (implant misplacement)" have been included as adverse drug reactions.
Pravafenix	fenofibrate/pravastatin	Laboratoires SMB S.A.	CHMP opinion recommending to update sections 4.4 and 4.8 of the SmPC with information on the new onset of diabetes. The package leaflet has been updated accordingly. The wording for this variation was agreed for all the Nationally Authorised Products by the PhVWP and is being implemented for the remaining Centrally Authorised Products.
Prialt	ziconotide	Eisai Ltd.	CHMP opinion recommending to update section 4.4 of the SmPC in the context of the 7 th annual reassessment to include a recommendation for patients to undergo a neuropsychiatric evaluation before and after starting intrathecal ziconotide.
Thalidomide Celgene	thalidomide	Celgene Europe Ltd.	CHMP opinion recommending to update sections 4.4 and 4.8 of the SmPC and the Package Leaflet with information on allergic reactions (angioedema/urticaria). A recommendation to discontinue thalidomide if a skin rash occurs has been included.
Tygacil	tigecycline	Pfizer Ltd.	CHMP opinion recommending to update sections 4.4 and 4.8 of the SmPC to additionally warn of the potential development of superinfection (the risk of which is increased in impaired healing of surgical wounds) and to add

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			impaired healing as adverse drug reaction.
Xgeva	denosumab	Amgen Europe B.V.	CHMP opinion recommending to update sections 4.2, 4.4 and 4.8 of the SmPC to include information on fatal cases of severe symptomatic hypocalcaemia, reported in the post-marketing setting. The CHMP endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.
Pradaxa	dabigatran etexilate mesilate	Boehringer Ingelheim International GmbH	CHMP Opinion recommending changes to sections 4.3, 4.4 and 4.5 of the SmPC in order to contraindicate the concomitant use of dronedarone and dabigatran following the results of the phase 1 drug-drug interaction study. In addition, fluconazole was deleted from the Package Leaflet.