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Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 14-17 January 2013

Name of medicine	INN	Marketing authorisation holder	Scope
Lucentis	ranibizumab	Novartis Europharm Ltd.	CHMP opinion to update SmPC sections 4.4 and 4.8 with a revised class warning in relation to the risk of systemic adverse events following intravitreal injection with VEGF inhibitors and to include stroke and myocardial infarction to the product-class-related adverse reactions as an example of arterial thromboembolic events.

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Neurobloc	botulinum toxin type B	Eisai Ltd.	CHMP opinion to update section 4.4 of the SmPC to include further information on the risk of systemic toxicity or spread of toxin following incorrect clinical use or off-label use. Sections 4.1, 4.2, 4.4, 4.8 and 4.9 of the SmPC have also been updated to highlight, in accordance with the SmPC guideline, that the product is not authorised in the paediatric population. The CHMP endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.
Prolia	denosumab	Amgen Europe B.V.	CHMP opinion to update sections 4.4 and 4.8 of the SmPC to include a new warning of rare cases of 'atypical femoral fracture'. The Package Leaflet has been updated accordingly. This follows rare cases of atypical femoral fracture observed in patients receiving Prolia in the ongoing extension study of the FREEDOM trial. The CHMP endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.
Stelara	ustekinumab	Janssen-Cilag International N.V.	CHMP opinion to update sections 4.4 and 4.8 of the SmPC regarding the need to monitor the appearance of non-melanoma skin cancer in all patients, particularly in those older than 60 years, in patients with a history of prolonged immunosuppressant therapy or in those with a history of PUVA treatment. Section 4.4 has also been updated with information that long term treatment with Stelara does not suppress the humoral immune response to pneumococcal polysaccharide or tetanus vaccines. These changes follow data from continuous treatment with ustekinumab for up to 5 years.

Name of medicine	INN	Marketing authorisation holder	Scope
Tractocile	atosiban	Ferring Pharmaceuticals A/S	CHMP opinion to update sections 4.4 and 4.8 of the SmPC with information on the risk of lung edema in cases of multiple pregnancies and concomitant administration of atosiban with other medicinal products with tocolytic activity.
Tysabri	natalizumab	Elan Pharma International Ltd.	CHMP opinion to update section 4.4 of the SmPC to recommend that patients and healthcare professionals should continue to be alert for any new signs and symptoms of Progressive Multifocal Leukoencephalopathy (PML) for approximately 6 months following the discontinuation of Tysabri. This update follows reports of PML after discontinuation of Tysabri in patients who did not have findings suggestive of PML at the time of discontinuation.