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Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 13-16 February 2012

Name of medicine	INN	Marketing authorisation holder	Scope
Arava Leflunomide Winthrop	leflunomide	Sanofi-Aventis Deutschland GmbH	CHMP opinion recommending to introduce in section 4.4 of the SmPC a warning for peripheral neuropathy (PNP). In addition, the frequency of PNP in section 4.8 is changed from “very rare” to “common”.
Benlysta	belimumab	Glaxo Group Ltd.	CHMP opinion recommending changes to sections 4.2, 4.4 and 4.8 of the SmPC in order to update the safety information regarding hypersensitivity and infusion reactions. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce minor editorial changes in section 5.1 and 6.6 of the SmPC and to update the list of local representatives in the Package Leaflet. The CHMP has endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.

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Brinavess	vernakalant hydrochloride	Merck Sharp & Dohme Ltd.	CHMP opinion recommending to update sections 4.2 and 4.4. of the SmPC following a safety review due to cases of serious hypotension and bradychardia during and immediately after infusion of Brinavess. The CHMP recommends monitoring patients for the duration of the infusion and at least 15 minutes after the completion of the infusion for signs and symptoms of a sudden decrease in blood pressure or heart rate.
Votrient	pazopanib	Glaxo Group Ltd.	CHMP opinion recommending to update sections 4.2, 4.3, 4.4 and 5.2 of the SmPC in order to include updated recommendations and pharmacokinetic data in hepatic impaired patients based on the results from the final report of study NCI 8063 (VEG110827). This variation application addresses Follow Up Measure (FUM) 006.