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Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 10-13 December 2012

Name of medicine	INN	Marketing authorisation holder	Scope
Gilenya	fingolimod	Novartis Europharm Ltd.	CHMP opinion to update section 4.4 of the SmPC (reference is also made in section 4.2) to extend the recommendations for repeat first dose monitoring of heart activity when treatment is interrupted: • for one day or more during the first 2 weeks of treatment, • for more than 7 days during weeks 3 and 4 of treatment, in addition to the current recommendation for repeat first does monitoring when treatment is interrupted for more than 2 weeks after at least 1 month of treatment. Furthermore, such monitoring should be repeated for the second dose in patients requiring pharmacological intervention following the first dose.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8669
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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			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 section 4.3 of the SmPC to include a new contraindication for prosthetic heart valve replacement. In addition section 5.1 was updated to include the description of the RE ALIGN study results. The summary of this opinion can be found on the European Medicines Agency's website under the 'December CHMP meeting highlights'.
Qutenza	capsaicin	Astellas Pharma Europe B.V.	CHMP opinion to update SmPC sections 4.2, 4.4, 4.8 and 6.6 to include adverse drug reactions 'second degree burns', 'accidental exposure' and related precaution for use, further to a signal detection and evaluation of the data submitted in the PSUR. The Product Information is updated accordingly.