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Press Office

## Opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures

Adopted at the CHMP meeting of 18-21 November 2013

**Table 1.** Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Firdapse</b> (AMIFAMPRIDINE) BioMarin Europe Ltd	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
<b>Naglazyme</b> (GALSULFASE) BioMarin Europe Ltd	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
<b>Prialt</b> (Ziconotide), Eisai Ltd	Positive Opinion	Recommending lifting exceptional circumstances

**Table 2.** Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Arzerra</b> (OFATUMUMAB), Glaxo Group Ltd	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
<b>BOSULIF</b> (BOSUTINIB), Pfizer Limited	Positive Opinion	Recommending renewal of conditional Marketing Authorisation

**Table 3.** Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>VELCADE</b> (BORTEZOMIB), Janssen-Cilag International N.V.	Positive Opinion	Unlimited validity
<b>Zebinix</b> (ESLICARBAZEPINE ACETATE), Bial - Portela & C <sup>a</sup> , S.A.	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
<b>Nimvastid</b> (RIVASTIGMINE), Krka d.d. Novo mesto	Positive Opinion	Unlimited validity

**Table 4.** Accelerated assessment procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Chemical	Treatment of patients with refractory indolent non-Hodgkin lymphoma but also alone or in combination, for the treatment of patients with relapsed chronic lymphocytic leukemia.	x	
Chemical	Treatment of chronic hepatitis C in adult patients with compensated liver disease	x	