



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 23-26 March 2015

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Ceplene , (histamine dihydrochloride) Meda AB	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Yondelis , (trabectedin) Pharma Mar, S.A.	Positive Opinion	Marketing Authorisation exceptional approval lifted

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
Erivedge , (vismodegib) Roche Registration Ltd	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
Fampyra , (fampridine) Biogen Idec Ltd.	Positive Opinion	Recommending renewal of conditional Marketing Authorisation



Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Myclausen , (mycophenolate mofetil) Herbert J. Pasauer GmbH	Positive Opinion	Unlimited validity
Nivestim , (filgrastim) Hospira UK Limited	Positive Opinion	Unlimited validity
Topotecan Hospira , (topotecan) HOSPIRA UK LIMITED	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Human coagulation factor x	Control and Prevention of Bleeding Episodes: FACTOR X is a blood coagulation factor indicated for control and prevention of bleeding episodes in adults and children (aged 12 years and above) with hereditary factor X deficiency. Perioperative Management: FACTOR X is indicated in the perioperative management in adults and children (aged 12 years and above) with hereditary factor X deficiency.	X	