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Press Office

Opinions on annual reassessments, 5-year renewals

Adopted at the CHMP meeting of 16-19 April 2012

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Zavesca (miglustat), Actelion Registration Ltd.	Positive Opinion	No remaining grounds for the Marketing Authorisation to remain under exceptional circumstances
Riloncept Regeneron (riloncept), Regeneron UK Limited	Positive Opinion	Marketing Authorisation remains under exceptional circumstances

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
N/A		

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Atriance (nelarabine), Glaxo Group Ltd.	Positive Opinion	Recommending additional renewal
Optimark (gadoversetamide), Covidien Deutschland GmbH	Positive Opinion	Recommending additional renewal
Siklos (hydroxycarbamide), Addmedica	Positive Opinion	Recommending additional renewal
alli (orlistat), Glaxo Group Ltd.	Positive Opinion	Recommending additional renewal



Name of medicinal product (INN) MAH	Outcome	Comments
Abseamed (Epoetin Alfa), Medice Arzneimittel Pütter GmbH & Co. KG	Positive Opinion	Unlimited validity
Binocrit (Epoetin Alfa), Sandoz GmbH	Positive Opinion	Unlimited validity
Epoetin alfa Hexal (Epoetin Alfa), Hexal AG	Positive Opinion	Unlimited validity
EVRA (Norelgestromin / Ethinyl Estradiol), Janssen-Cilag International N.V.	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 metastatic colorectal carcinoma	X	