



24 October 2013
EMA/653489/2013
Press Office

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

Adopted at the CHMP meeting of 21-24 October 2013

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Aldurazyme (laronidase) Genzyme Europe BV	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Atriance (nelarabine) Glaxo Group Ltd	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
Caprelsa (vandetanib) AstraZeneca AB	Positive Opinion	Recommending renewal of conditional Marketing Authorisation

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Diacomit (Stiripentol) Biocodex	Positive Opinion	Unlimited validity
Advate (octocog alfa) Baxter AG	Positive Opinion	Unlimited validity
Bonviva (ibandronic acid) Roche	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Nplate (romiplostim) Amgen Europe B.V.	Positive Opinion	Unlimited validity
Removab (catumaxomab) Fresenius Biotech GmbH	Positive Opinion	Unlimited validity
Ribavirin Teva (ribavirin) Teva Pharma B.V.	Positive Opinion	Unlimited validity
Ribavirin Teva Pharma BV (ribavirin) Teva Pharma B.V.	Positive Opinion	Unlimited validity
Evicel (human fibrinogen, human thrombin) Omrix Biopharmaceuticals N. V	Positive Opinion	Recommending additional renewal
Mepact (mifamurtide) IDM Pharma S.A.S.	Positive Opinion	Recommending additional renewal

Table 4. Accelerated assessment procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Chemical	Treatment of adult patients with relapsed or refractory mantle cell lymphoma		x
Chemical	Treatment of genotype-1 chronic hepatitis C virus infection	x	